MEDICAL POLICY

SUBJECT: Orthopedic Footwear

HCPCS CODES:

The appearance of a code in this section does not necessarily indicate coverage.

L3000	Foot, insert, removable, molded to patient model, "UCB" type, Berkeley shell, each
L3001	Foot, insert, removable, molded to patient model, Spenco, each
L3002	Foot, insert, removable, molded to patient model, plastazote or equal, each
L3003	Foot, insert, removable, molded to patient model, silicone gel, each
L3010	Foot, insert, removable, molded to patient model, longitudinal arch support, each
L3020	Foot, insert, removable, molded to patient model, longitudinal/metatarsal support, each
L3030	Foot, insert, removable, formed to patient foot, each
L3040	Foot, arch support, removable, premolded, longitudinal, each
L3050	Foot, arch support, removable, premolded, metatarsal, each
L3060	Foot, arch support, removable, premolded longitudinal/metatarsal, each
L3070	Foot, arch support, non-removable, attached to shoe, longitudinal, each
L3080	Foot, arch support, non-removable, attached to shoe, metatarsal, each
L3090	Foot, arch support, non-removable, attached to shoe longitudinal/metatarsal, each
L3100	Hallus-valgus night dynamic splint
L3140	Foot, abduction rotation bar, including shoes
L3150	Foot, abduction rotation bar, without shoes
L3160	Foot, adjustable shoe styled positioning device
L3170	Foot, plastic heel stabilizer
L3201	Orthopedic shoe, oxford with supinator or pronator, infant
L3202	Orthopedic shoe, oxford with supinator or pronator, child
L3203	Orthopedic shoe, oxford with supinator or pronator, junior
L3204	Orthopedic shoe, hightop with supinator or pronator, infant
L3206	Orthopedic shoe, hightop with supinator or pronator, child
L3207	Orthopedic shoe, hightop with supinator or pronator, junior
L3208	Surgical boot, each, infant
L3209	Surgical boot, each, child
L3211	Surgical boot, each, junior
L3212	Benesch boot, pair, infant
L3213	Benesch boot, pair, child
L3214	Benesch boot, pair, junior
L3215	Orthopedic footwear, ladies shoes, oxford
L3216	Orthopedic footwear, ladies shoes, depth inlay
L3217	Orthopedic footwear, ladies shoes, hightop, depth inlay
L3218	Orthopedic footwear, ladies surgical boot, each
L3219	Orthopedic footwear, mens shoes, oxford
L3221	Orthopedic footwear, mens shoes, depth inlay
L3222	Orthopedic footwear, mens shoes, hightop, depth inlay
L3223	Orthopedic footwear, mens surgical boot, each
L3224	Orthopedic footwear, woman's shoe, oxford, used as an integral part of a brace (orthosis)
L3225	Orthopedic footwear, man's shoe, oxford, used as an integral part of a brace (orthosis)
L3230	Orthopedic footwear, custom shoes, depth inlay
L3250	Orthopedic footwear, custom molded shoe, removable inner mold, prosthetic shoe, each
L3251	Foot, shoe molded to patient model, silicone shoe, each
L3252	Foot, shoe molded to patient model, plastazote (or similar), custom fabricated, each
L3253	Foot, molded shoe plastazote (or similar) custom fitted, each
L3254	Non-standard size or width
L3255	Non-standard size or length

L3257	Orthopedic footwear, additional charge for split size
L3260	Ambulatory surgical boot, each
L3265	Plastazote sandal, each
L3300	Lift, elevation, heel, tapered to metatarsals, per inch
L3310	Lift, elevation, heel and sole, neoprene, per inch
L3320	Lift, elevation, heel and sole, cork, per inch
L3330	Lift, elevation, metal extension (skate)
L3332	Lift, elevation, inside shoe, tapered, up to one-half inch
L3334	Lift, elevation, heel, per inch
L3340	Heel wedge, SACH
L3350	Heel wedge
L3360	Sole wedge, outside sole
L3370	Sole wedge, between sole
L3380	Clubfoot wedge
L3390	Outflare wedge
L3400	Metatarsal bar wedge, rocker
L3410	Metatarsal bar wedge, between sole
L3420	Full sole and heel wedge, between sole
L3430	Heel, counter, plastic reinforced
L3440	Heel, counter, leather reinforced
L3450	Heel, SACH cushion type
L3455	Heel, new leather, standard
L3460	Heel, new rubber, standard
L3465	Heel, Thomas with wedge
L3470	Heel, Thomas extended to ball
L3480	Heel, pad and depression for spur
L3485	Heel, pad, removable for spur
L3500	Orthopedic shoe addition, insole, leather
L3510	Orthopedic shoe addition, insole, rubber
L3520	Orthopedic shoe addition, insole, felt covered with leather
L3530	Orthopedic shoe addition, sole, half
L3540	Orthopedic shoe addition, sole, full
L3550	Orthopedic shoe addition, toe tap, standard
L3560	Orthopedic shoe addition, toe tap, horseshoe
L3570	Orthopedic shoe addition, special extension to instep (leather with eyelets)
L3580	Orthopedic shoe addition, convert instep to velcro closure
L3590	Orthopedic shoe addition, convert firm shoe counter to soft counter
L3595	Orthopedic shoe addition, March bar
L3600	Transfer of an orthosis from one shoe to another, caliper plate, existing
L3610	Transfer of an orthosis from one shoe to another, caliper plate, new
L3620	Transfer of an orthosis from one shoe to another, solid stirrup, existing
L3630	Transfer of an orthosis from one shoe to another, solid stirrup, new
L3640	Transfer of an orthosis from one shoe to another, Dennis Browne splint (Riveton), both shoes
L3649	Orthopedic shoe, modification, addition or transfer, not otherwise specified

HCPCS MODIFIERS:

KX	Specific required documentation on file
LT	Left side
RT	Right side

BENEFIT CATEGORY: Braces (Orthotics), Artificial Limbs

REFERENCE: Coverage Issues Manual 70-3

COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must (1) be eligible for a defined Medicare benefit category, (2) be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member, and (3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following coverage and payment rules.

Shoes, inserts, and modifications are covered in limited circumstances. They are covered in selected patients with diabetes for the prevention or treatment of diabetic foot ulcers. However, different codes (A5500-A5511) are used for footwear provided under this benefit. See the medical policy on Therapeutic Shoes for Diabetics for details.

Shoes are also covered if they are an integral part of a covered leg brace described by codes L1900, L1920, L1980-L2030, L2050, L2060, L2080, or L2090. Oxford shoes (L3224, L3225) are covered in these situations. Other shoes, e.g. high top, depth inlay or custom for non-diabetics, etc. (L3649), are also covered if they are an integral part of a covered brace and if they are medically necessary for the proper functioning of the brace. Heel replacements (L3455, L3460), sole replacements (L3530, L3540), and shoe transfers (L3600-L3640) involving shoes on a covered brace are also covered. Inserts and other shoe modifications (L3000-L3170, L3300-L3450, L3465-L3520, L3550-L3595) are covered if they are on a shoe that is an integral part of a covered brace and if they are medically necessary for the proper functioning of the brace. Shoes and related modifications, inserts, heel/sole replacements or shoe transfers billed without a KX modifier will be denied as noncovered because coverage is statutorily excluded.

According to a national policy determination, a shoe and related modifications, inserts, and heel/sole replacements, are covered only when the shoe is an integral part of a brace. A matching shoe which is not attached to a brace and items related to that shoe must not be billed with a KX modifier and will be denied as noncovered because coverage is statutorily excluded.

Shoes which are incorporated into a brace must be billed by the same supplier billing for the brace. Shoes which are billed separately (i.e., not as part of a brace) will be denied as noncovered. A KX modifier must not be used in this situation.

Prosthetic shoes (L3250) are covered if they are an integral part of a prosthesis for patients with a partial foot amputation (ICD-9 diagnosis codes 755.31, 755.38, 755.39, 895.0-896.3). Claims for prosthetic shoes for other ICD-9 diagnosis codes will be denied as not medically necessary.

Shoes are denied as noncovered when they are put on over a partial foot prosthesis or other lower extremity prosthesis (L5010-L5600) which is attached to the residual limb by other mechanisms because there is no Medicare benefit for these items.

With the exception of the situations described above, orthopedic footwear billed using codes L3000-L3649 will be denied as noncovered.

CODING GUIDELINES:

Oxford shoes that are an integral part of a brace are billed using codes L3224 or L3225 with a KX modifier. For these codes, one unit of service is each shoe. Oxford shoes that are not part of a leg brace must be billed with codes L3215 or L3219 without a KX modifier.

Other shoes (e.g., high top, depth inlay or custom shoes for non-diabetics, etc.) that are an integral part of a brace are billed using code L3649 with a KX modifier. Other shoes that are not an integral

part of a brace must be billed using codes L3216, L3217, L3221, L3222, L3230, L3251-L3253, or L3649 without a KX modifier.

Depth-inlay or custom molded shoes for diabetics (A5500-A5501) and related inserts and modifications (A5503-A5511) are billed using these A codes whether or not the shoe is an integral part of a brace. (See policy on Therapeutic Shoes for Diabetics for coverage, documentation, and additional coding guidelines.)

Code L3250 may be used only for a shoe that is custom fabricated from a model of a patient and has a removable custom fabricated insert designed for toe or distal partial foot amputation. The shoe serves to hold the insert on the leg. Code L3250 must not be used for a shoe that is put on other types of leg prostheses (L5010-L5600) that are attached to the residual limb by other mechanisms.

The right (RT) and left (LT) modifiers must be used with footwear codes. When bilateral items are provided on the same date of service, bill both on the same claim line using the LTRT modifier and 2 units of service.

Suppliers should refer to the Statistical Analysis DME Regional Carrier (SADMERC) web site or contact the SADMERC for guidance on the correct coding for these items.

DOCUMENTATION:

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. § 1395l(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

An order for the shoe and related modifications and inserts must be signed and dated by the treating physician and kept on file by the supplier. An order is not required for a heel or sole replacement or transfer of a shoe to a brace.

When billing for a shoe that is an integral part of a leg brace or for related modifications, inserts, heel/sole replacements or shoe transfer, a KX modifier must be added to the code. If the shoe or related item is not an integral part of a leg brace, the KX modifier must not be used.

When billing for prosthetic shoes (L3250) and related items, an ICD-9 diagnosis code (specific to the 5th digit), describing the condition which necessitates the prosthetic shoes, must be included on each order and on each claim for the prosthetic shoes and related items.

When code L3649 with a KX modifier is billed, the claim must include a narrative description of the item provided as well as a brief statement of the medical necessity for the item. This must be attached to a hard copy claim or entered in the HA0 record of an electronic claim.

Refer to the Supplier Manual for more information on orders, medical records, and supplier documentation.

EFFECTIVE DATE: Claims with dates of service on or after July 1, 2002.

This is a revision of a previously published policy.

General Information
Supplier Enrollment
Ombudsman Contacts
FAQs
Coverage
Certificates of Medical Necessity
Physician Information Sheets
SADMERC
Advisories
Manuals
Medical Policies
Fee Schedules
Forms
Appeals
Benefit Integrity
Learning & Education
Related Sites
DMERC Home
Providers Home

Manuals

<<BACK

Chapter 58 - Orthopedic Footwear

View Attachments

Chapter 58 contains the medical policy for orthopedic footwear. Click on View Attachments to download the entire chapter for viewing and printing in PDF format.

MEDICAL POLICY

SUBJECT: Orthopedic Footwear

HCPCS CODES:

The appearance of a code in this section does not necessarily indicate coverage.

L3000 Foot, insert, removable, molded to patient model, "UCB" type, Berkeley shell, each
L3001 Foot, insert, removable, molded to patient model, Spenco, each
L3002 Foot, insert, removable, molded to patient model, plastazote or equal, each
L3003 Foot, insert, removable, molded to patient model, silicone gel, each
L3010 Foot, insert, removable, molded to patient model, longitudinal arch support, each
L3020 Foot, insert, removable, molded to patient model, longitudinal/metatarsal support, each
L3030 Foot, insert, removable, formed to patient foot, each
L3040 Foot, arch support, removable, premolded, longitudinal, each
L3050 Foot, arch support, removable, premolded, metatarsal, each
L3060 Foot, arch support, removable, premolded longitudinal/metatarsal, each
L3070 Foot, arch support, non-removable, attached to shoe, longitudinal, each

L3080 Foot, arch support, non-removable, attached to shoe, metatarsal, each
L3090 Foot, arch support, non-removable, attached to shoe longitudinal/metatarsal, each
L3100 Hallus-valgus night dynamic splint
L3140 Foot, abduction rotation bar, including shoes
L3150 Foot, abduction rotation bar, without shoes
L3160 Foot, adjustable shoe styled positioning device
L3170 Foot, plastic heel stabilizer
L3201 Orthopedic shoe, oxford with supinator or pronator, infant
L3202 Orthopedic shoe, oxford with supinator or pronator, child
L3203 Orthopedic shoe, oxford with supinator or pronator, junior
L3204 Orthopedic shoe, hightop with supinator or pronator, infant
L3206 Orthopedic shoe, hightop with supinator or pronator, child
L3207 Orthopedic shoe, hightop with supinator or pronator, junior
L3208 Surgical boot, each, infant
L3209 Surgical boot, each, child
L3211 Surgical boot, each, junior
L3212 Benesch boot, pair, infant
L3213 Benesch boot, pair, child
L3214 Benesch boot, pair, junior
L3215 Orthopedic footwear, ladies shoes, oxford
L3216 Orthopedic footwear, ladies shoes, depth inlay
L3217 Orthopedic footwear, ladies shoes, hightop, depth inlay
L3218 Orthopedic footwear, ladies surgical boot, each
L3219 Orthopedic footwear, mens shoes, oxford
L3221 Orthopedic footwear, mens shoes, depth inlay
L3222 Orthopedic footwear, mens shoes, hightop, depth inlay
L3223 Orthopedic footwear, mens surgical boot, each
L3224 Orthopedic footwear, woman's shoe, oxford, used as an integral part of a brace (orthosis)
L3225 Orthopedic footwear, man's shoe, oxford, used as an integral part of a brace (orthosis)
L3230 Orthopedic footwear, custom shoes, depth inlay
L3250 Orthopedic footwear, custom molded shoe, removable inner mold, prosthetic shoe, each
L3251 Foot, shoe molded to patient model, silicone shoe, each
L3252 Foot, shoe molded to patient model, plastazote (or similar), custom fabricated, each
L3253 Foot, molded shoe plastazote (or similar) custom fitted, each
L3254 Non-standard size or width
L3255 Non-standard size or length
L3257 Orthopedic footwear, additional charge for split size
L3260 Ambulatory surgical boot, each
L3265 Plastazote sandal, each
L3300 Lift, elevation, heel, tapered to metatarsals, per inch
L3310 Lift, elevation, heel and sole, neoprene, per inch
L3320 Lift, elevation, heel and sole, cork, per inch
L3330 Lift, elevation, metal extension (skate)
L3332 Lift, elevation, inside shoe, tapered, up to one-half inch
L3334 Lift, elevation, heel, per inch

L3340 Heel wedge, SACH
L3350 Heel wedge
L3360 Sole wedge, outside sole
L3370 Sole wedge, between sole
L3380 Clubfoot wedge
L3390 Outflare wedge
L3400 Metatarsal bar wedge, rocker
L3410 Metatarsal bar wedge, between sole
L3420 Full sole and heel wedge, between sole
L3430 Heel, counter, plastic reinforced
L3440 Heel, counter, leather reinforced
L3450 Heel, SACH cushion type
L3455 Heel, new leather, standard
L3460 Heel, new rubber, standard
L3465 Heel, Thomas with wedge
L3470 Heel, Thomas extended to ball
L3480 Heel, pad and depression for spur
L3485 Heel, pad, removable for spur
L3500 Orthopedic shoe addition, insole, leather
L3510 Orthopedic shoe addition, insole, rubber
L3520 Orthopedic shoe addition, insole, felt covered with leather
L3530 Orthopedic shoe addition, sole, half
L3540 Orthopedic shoe addition, sole, full
L3550 Orthopedic shoe addition, toe tap, standard
L3560 Orthopedic shoe addition, toe tap, horseshoe
L3570 Orthopedic shoe addition, special extension to instep (leather with eyelets)
L3580 Orthopedic shoe addition, convert instep to velcro closure
L3590 Orthopedic shoe addition, convert firm shoe counter to soft counter
L3595 Orthopedic shoe addition, March bar
L3600 Transfer of an orthosis from one shoe to another, caliper plate, existing
L3610 Transfer of an orthosis from one shoe to another, caliper plate, new
L3620 Transfer of an orthosis from one shoe to another, solid stirrup, existing
L3630 Transfer of an orthosis from one shoe to another, solid stirrup, new
L3640 Transfer of an orthosis from one shoe to another, Dennis Browne splint (Riveton), both shoes
L3649 Orthopedic shoe, modification, addition or transfer, not otherwise specified

HCPCS MODIFIERS:

KX Specific required documentation on file
LT Left side
RT Right side

BENEFIT CATEGORY: Braces (Orthotics), Artificial Limbs

REFERENCE: Coverage Issues Manual 70-3

COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must (1) be eligible for a defined Medicare benefit category, (2) be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member, and (3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following coverage and payment rules.

Shoes, inserts, and modifications are covered in limited circumstances. They are covered in selected patients with diabetes for the prevention or treatment of diabetic foot ulcers. However, different codes (A5500-A5511) are used for footwear provided under this benefit. See the medical policy on Therapeutic Shoes for Diabetics for details.

Shoes are also covered if they are an integral part of a covered leg brace described by codes L1900, L1920, L1980-L2030, L2050, L2060, L2080, or L2090. Oxford shoes (L3224, L3225) are covered in these situations. Other shoes, e.g. high top, depth inlay or custom for non-diabetics, etc. (L3649), are also covered if they are an integral part of a covered brace and if they are medically necessary for the proper functioning of the brace. Heel replacements (L3455, L3460), sole replacements (L3530, L3540), and shoe transfers (L3600-L3640) involving shoes on a covered brace are also covered. Inserts and other shoe modifications (L3000-L3170, L3300-L3450, L3465-L3520, L3550-L3595) are covered if they are on a shoe that is an integral part of a covered brace and if they are medically necessary for the proper functioning of the brace. Shoes and related modifications, inserts, heel/sole replacements or shoe transfers billed without a KX modifier will be denied as noncovered because coverage is statutorily excluded.

According to a national policy determination, a shoe and related modifications, inserts, and heel/sole replacements, are covered only when the shoe is an integral part of a brace. A matching shoe which is not attached to a brace and items related to that shoe must not be billed with a KX modifier and will be denied as noncovered because coverage is statutorily excluded.

Shoes which are incorporated into a brace must be billed by the same supplier billing for the brace. Shoes which are billed separately (i.e., not as part of a brace) will be denied as noncovered. A KX modifier must not be used in this situation.

Prosthetic shoes (L3250) are covered if they are an integral part of a prosthesis for patients with a partial foot amputation (ICD-9 diagnosis codes 755.31, 755.38, 755.39, 895.0-896.3). Claims for prosthetic shoes for other ICD-9 diagnosis codes will be denied as not medically necessary.

Shoes are denied as noncovered when they are put on over a partial foot prosthesis or other lower extremity prosthesis (L5010-L5600) which is attached to the residual limb by other mechanisms because there is no Medicare benefit for these items.

With the exception of the situations described above, orthopedic footwear billed using codes L3000-L3649 will be denied as noncovered.

CODING GUIDELINES:

Oxford shoes that are an integral part of a brace are billed using codes L3224 or L3225 with a KX modifier. For these codes, one unit of service is each shoe. Oxford shoes that are not part of a leg brace must be billed with codes L3215 or L3219 without a KX modifier.

Other shoes (e.g., high top, depth inlay or custom shoes for non-diabetics, etc.) that are an integral part of a brace are billed using code L3649 with a KX modifier. Other shoes that are not an integral part of a brace must be billed using codes L3216, L3217, L3221, L3222, L3230, L3251-L3253, or L3649 without a KX modifier.

Depth-inlay or custom molded shoes for diabetics (A5500-A5501) and related inserts and modifications (A5503-A5511) are billed using these A codes whether or not the shoe is an integral part of a brace. (See policy on Therapeutic Shoes for Diabetics for coverage, documentation, and additional coding guidelines.)

Code L3250 may be used only for a shoe that is custom fabricated from a model of a patient and has a removable custom fabricated insert designed for toe or distal partial foot amputation. The shoe serves to hold the insert on the leg. Code L3250 must not be used for a shoe that is put on other types of leg prostheses (L5010-L5600) that are attached to the residual limb by other mechanisms.

The right (RT) and left (LT) modifiers must be used with footwear codes. When bilateral items are provided on the same date of service, bill both on the same claim line using the LTRT modifier and 2 units of service.

Suppliers should refer to the Statistical Analysis DME Regional Carrier (SADMERC) web site or contact the SADMERC for guidance on the correct coding for these items.

DOCUMENTATION:

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42

U.S.C. § 1395l(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

An order for the shoe and related modifications and inserts must be signed and dated by the treating physician and kept on file by the supplier. An order is not required for a heel or sole replacement or transfer of a shoe to a brace.

When billing for a shoe that is an integral part of a leg brace or for related modifications, inserts, heel/sole replacements or shoe transfer, a KX modifier must be added to the code. If the shoe or related item is not an integral part of a leg brace, the KX modifier must not be used.

When billing for prosthetic shoes (L3250) and related items, an ICD-9 diagnosis code (specific to the 5th digit), describing the condition which necessitates the prosthetic shoes, must be included on each order and on each claim for the prosthetic shoes and related items.

When code L3649 with a KX modifier is billed, the claim must include a narrative description of the item provided as well as a brief statement of the medical necessity for the item. This must be attached to a hard copy claim or entered in the HA0 record of an electronic claim.

Refer to the Supplier Manual for more information on orders, medical records, and supplier documentation.

EFFECTIVE DATE: Claims with dates of service on or after July 1, 2002.

This is a revision of a previously published policy.

<<<BACK

Region C DMEPOS Supplier Manual (updated through Autumn 2002)
....Change of Address Notification Form
....Contents
....Index
....Part I - General Information
.....Chapter 1 - Beneficiary Eligibility & Supplier Responsibility
.....Chapter 2 - Jurisdiction
.....Chapter 3 - National Supplier Clearinghouse
.....Chapter 4 - Statistical Analysis DMERC
.....Chapter 5 - Claims Filing
.....Chapter 6 - Documentation Requirements
.....Chapter 7 - Advance Beneficiary Notice
.....Chapter 8 - Durable Medical Equipment
.....Chapter 9 - Pricing
.....Chapter 10 - Claim Payment
.....Chapter 11 - Medicare Assignment Agreement

General Information
Supplier Enrollment
Ombudsman Contacts
FAQs
Coverage
Certificates of Medical Necessity
Physician Information Sheets
SADMERC
Advisories
Manuals
Medical Policies
Fee Schedules
Forms
Appeals
Benefit Integrity
Learning & Education
Related Sites
DMERC Home
Providers Home

Manuals

<<BACK

Chapter 59 - Facial Prostheses

View Attachments

Chapter 59 contains the medical policy for facial prostheses. Click on View Attachments to download the entire chapter for viewing and printing in PDF format.

MEDICAL POLICY

SUBJECT: Facial Prostheses

HCPCS CODES:

The appearance of a code in this section does not necessarily indicate coverage.

A4364	Adhesive, liquid or equal, any type, per ounce
A4365	Adhesive remover wipes, any type, per 50
A4455	Adhesive remover or solvent (for tape, cement or other adhesive), per ounce
K0572	Tape, non-waterproof, per 18 square inches
K0573	Tape, waterproof, per 18 square inches
L8040	Nasal prosthesis, provided by a non-physician
L8041	Midfacial prosthesis, provided by a non-physician
L8042	Orbital prosthesis, provided by a non-physician
L8043	Upper facial prosthesis, provided by a non-physician
L8044	Hemi-facial prosthesis, provided by a non-physician
L8045	Auricular prosthesis, provided by a non-physician
L8046	Partial facial prosthesis, provided by a non-physician
L8047	Nasal septal prosthesis, provided by a non-physician
L8048	Unspecified maxillofacial prosthesis, by report, provided by a

	non-physician
L8049	Repair or modification of maxillofacial prosthesis, labor component, 15 minute increments, provided by a non-physician
V2623	Prosthetic eye, plastic, custom
V2629	Prosthetic eye, other type

HCPCS MODIFIERS

KM Replacement of facial prosthesis including new impression/moulage

KN Replacement of facial prosthesis using previous master model

LT Left side

RT Right side

BENEFIT CATEGORY: Prosthetic Devices

DEFINITION

A nasal prosthesis (L8040) is a removable superficial prosthesis which restores all or part of the nose. It may include the nasal septum.

A midfacial prosthesis (L8041) is a removable superficial prosthesis which restores part or all of the nose plus significant adjacent facial tissue/structures, but does not include the orbit or any intraoral maxillary component. Adjacent facial tissue/structures include one or more of the following: soft tissue of the cheek, upper lip, or forehead.

An orbital prosthesis (L8042) is a removable superficial prosthesis which restores the eyelids and the hard and soft tissue of the orbit. It may also include the eyebrow. This code does not include the ocular prosthesis component.

An upper facial prosthesis (L8043) is a removable superficial prosthesis which restores the orbit plus significant adjacent facial tissue/structures, but does not include the nose or any intraoral maxillary component. Adjacent facial tissue/structures include one or more of the following: soft tissue of the cheek or forehead. This code does not include the ocular prosthesis component.

A hemi-facial prosthesis (L8044) is a removable superficial prosthesis which restores part or all of the nose plus the orbit plus significant adjacent facial tissue/structures, but does not include any intraoral maxillary component. This code does not include the ocular prosthesis component.

An auricular prosthesis (L8045) is a removable superficial prosthesis which restores all or part of the ear.

A partial facial prosthesis (L8046) is a removable superficial prosthesis which restores a portion of the face but which does not specifically involve the nose, orbit or ear.

A nasal septal prosthesis (L8047) is a removable prosthesis which occludes a hole in the nasal septum but does not include superficial nasal tissue.

Code V2623 describes an ocular prosthesis which is custom fabricated.

COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following coverage and payment rules.

A facial prosthesis is covered when there is loss or absence of facial tissue due to disease, trauma, surgery, or a congenital defect.

Adhesives, adhesive remover, and tape used in conjunction with a facial prosthesis are covered. Other skin care products related to the prosthesis, including but not limited to cosmetics, skin cream, cleansers, etc., are non-covered.

The following services and items are included in the allowance for a facial prosthesis and, therefore, are not separately billable to or payable by Medicare under the prosthetic device benefit:

- Evaluation of the patient
- Pre-operative planning
- Cost of materials
- Labor involved in the fabrication and fitting of the prosthesis
- Modifications to the prosthesis made at the time delivery of the prosthesis or within 90 days thereafter
- Repair due to normal wear or tear within 90 days of delivery
- Follow-up visits within 90 days of delivery of the prosthesis

Modifications to a prosthesis are separately payable when they occur more than 90 days after delivery of the prosthesis and they are required because of a change in the patient's condition.

Repairs are covered when there has been accidental damage or extensive wear to the prosthesis that can be repaired. If the expense for repairs exceeds the estimated expense for a replacement prosthesis, no payments can be made for the amount of the excess.

Follow-up visits which occur more than 90 days after delivery and which do not involve modification or repair of the prosthesis are non-covered services.

Replacement of a facial prosthesis is covered in cases of loss or irreparable damage or wear or when required because of a change in the patient's condition that cannot be accommodated by modification of the existing prosthesis. When replacement involves a new impression/moulage rather than use of a previous master model, the reason for the new impression/moulage must be clearly documented in the supplier's records and be available to the DMERC on request.

Claims for facial prostheses from nonphysicians provided in an office or nursing home setting are submitted to the DMERC. Claims for facial prostheses from physicians in these settings are submitted to the local carrier. Claims for facial prostheses provided in an outpatient hospital setting are submitted to the local intermediary. Facial prostheses provided in an inpatient hospital setting are included in the payment made to the hospital and therefore should not be submitted to the DMERC. Implanted prosthesis anchoring components should not be billed to the DMERC.

If an ocular prosthesis is dispensed to the patient as an integral part of a facial prosthesis, the ocular prosthesis component must be billed by the supplier of the facial prosthesis. (For information on ocular prostheses that are not part of orbital prostheses, refer to the medical policy on Eye Prostheses.)

CODING GUIDELINES

When a replacement prosthesis is fabricated starting with a new impression/moulage, the KM modifier should be added to the code. When a replacement prosthesis is fabricated using a previous master model, the KN modifier should be added to the code.

Covered modifications or repairs are billed using code L8049 for the labor components and Code K0448 for any materials used. Time reported using code L8049 should only be for laboratory modification/repair time and associated prosthetic evaluation used only for services after 90 days from the date of delivery of the prosthesis. Evaluation not associated with repair or modification is non-covered and should not be coded as L8049.

Adhesives, adhesive remover, and tape used in conjunction with a facial prosthesis should be billed using codes A4364, A4455, A4365, K0572 or K0573. The unit of service is specified for each code. For tape, one unit of service is 18 square inches. Therefore, a roll of tape 1/2" X 3 yds. would be 3 units; 1" x 3 yds. would be 6 units. Other skin care products related to the prosthesis should generally not be billed to the DMERC, but if they are billed at the beneficiary's request, code A9270 (non-covered item or service) should be used.

When a new ocular prosthesis component is provided as an integral part of an orbital, upper facial or hemi-facial prosthesis, it should be billed using code V2623 or V2629 on a separate claim line. When a replacement facial prosthesis utilizes an ocular component from the prior prosthesis, the ocular prosthesis code should not be billed.

If a facial prosthesis has a component which is used to attach it to a bone-anchored implant or to an internal prosthesis (e.g. maxillary obturator), that component should be billed separately using code L8048. This code should not be used for implanted prosthesis anchoring components.

Code L8048 is also used for a facial prosthesis that is not described by a specific code, L8040-L8047.

Code V2629 is used for an ocular prosthesis that is not custom fabricated (i.e. stock prosthesis).

When a prothesis is needed for adjacent facial regions, a single code must be used to bill for the item whenever possible. For example, if a defect involves the nose and orbit, this should be billed using the hemi-facial prosthesis code and not separate codes for the orbit and nose. This would apply even if the prosthesis is fabricated in two separate parts.

The right (RT) and left (LT) modifiers should be used with facial prosthesis codes when applicable. If bilateral prostheses using the same code are billed on the same date of service, the code should be entered on a single claims line using the LTRT modifiers and billed with 2 units of service.

Suppliers should refer to the Statistical Analysis DME Regional Carrier (SADMERC) web site or contact the SADMERC for guidance on the correct coding for these items.

Documentation

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. § 1395l(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

An order for the initial prosthesis and/or related supplies which is signed and dated by the treating physician must be kept on file by the prosthetist/supplier. A separate physician order is not required for subsequent modifications, repairs or replacement of a facial prosthesis. A new order is required when different supplies are ordered.

When codes A4455, K0572, K0573, or A4365 are billed for supplies used in conjunction with a facial prosthesis, ICD-9 diagnosis code V43.89 should also be included on each claim.

A photograph of the prosthesis and a photograph of the patient without the prosthesis must be retained in the supplier's record and be available to the DMERC on request.

When code L8048 is used for a miscellaneous prosthesis or prosthetic component, the claim must be accompanied by a clear description and a drawing/copy of photograph of the item provided and the medical necessity.

When code V2629 is billed, the claim must be accompanied by a complete description of the item.

Claims for replacement, repair or modification of a facial prosthesis must include an explanation of the reason for the service.

When additional documentation is required, it should be entered in the HA0 record of an electronic claim or attached to a paper claim.

Refer to the Supplier Manual for more information on orders, medical records and supplier documentation.

Effective Date: Claims with dates of service on or after July 1, 2002.

This is a revision of a previously published policy.

«BACK

Region C DMEPOS Supplier Manual (updated through Autumn 2002)
....Change of Address Notification Form
....Contents
....Index
....Part I - General Information
.....Chapter 1 - Beneficiary Eligibility & Supplier Responsibility
.....Chapter 2 - Jurisdiction
.....Chapter 3 - National Supplier Clearinghouse
.....Chapter 4 - Statistical Analysis DMERC
.....Chapter 5 - Claims Filing
.....Chapter 6 - Documentation Requirements
.....Chapter 7 - Advance Beneficiary Notice
.....Chapter 8 - Durable Medical Equipment
.....Chapter 9 - Pricing
.....Chapter 10 - Claim Payment
.....Chapter 11 - Medicare Assignment Agreement
.....Chapter 12 - Medicare as Secondary Payer
.....Chapter 13 - Multifunctional Teams & Professional Relations
.....Chapter 14 - Appeals Process
.....Chapter 15 - Fraud & Abuse

MEDICAL POLICY

SUBJECT: Facial Prostheses

HCPCS CODES:

The appearance of a code in this section does not necessarily indicate coverage.

A4364	Adhesive, liquid or equal, any type, per ounce
A4365	Adhesive remover wipes, any type, per 50
A4455	Adhesive remover or solvent (for tape, cement or other adhesive), per ounce
K0572	Tape, non waterproof, per 18 square inches
K0573	Tape, waterproof, per 18 square inches
L8040	Nasal prosthesis, provided by a non-physician
L8041	Midfacial prosthesis, provided by a non-physician
L8042	Orbital prosthesis, provided by a non-physician
L8043	Upper facial prosthesis, provided by a non-physician
L8044	Hemi facial prosthesis, provided by a non-physician
L8045	Auricular prosthesis, provided by a non-physician
L8046	Partial facial prosthesis, provided by a non-physician
L8047	Nasal septal prosthesis, provided by a non-physician
L8048	Unspecified maxillofacial prosthesis, by report, provided by a non-physician
L8049	Repair or modification of maxillofacial prosthesis, labor component, 15 minute increments, provided by a non-physician
V2623	Prosthetic eye, plastic, custom
V2629	Prosthetic eye, other type

HCPCS MODIFIERS

KM	Replacement of facial prosthesis including new impression/moulage
KN	Replacement of facial prosthesis using previous master model
LT	Left side
RT	Right side

BENEFIT CATEGORY: Prosthetic Devices

DEFINITION

A nasal prosthesis (L8040) is a removable superficial prosthesis which restores all or part of the nose. It may include the nasal septum.

A midfacial prosthesis (L8041) is a removable superficial prosthesis which restores part or all of the nose plus significant adjacent facial tissue/structures, but does not include the orbit or any intraoral maxillary component. Adjacent facial tissue/structures include one or more of the following: soft tissue of the cheek, upper lip, or forehead.

An orbital prosthesis (L8042) is a removable superficial prosthesis which restores the eyelids and the hard and soft tissue of the orbit. It may also include the eyebrow. This code does not include the ocular prosthesis component.

An upper facial prosthesis (L8043) is a removable superficial prosthesis which restores the orbit plus significant adjacent facial tissue/structures, but does not include the nose or any intraoral maxillary component. Adjacent facial tissue/structures include one or more of the following: soft tissue of the cheek or forehead. This code does not include the ocular prosthesis component.

A hemi-facial prosthesis (L8044) is a removable superficial prosthesis which restores part or all of the nose plus the orbit plus significant adjacent facial tissue/structures, but does not include any intraoral maxillary component. This code does not include the ocular prosthesis component.

An auricular prosthesis (L8045) is a removable superficial prosthesis which restores all or part of the ear.

A partial facial prosthesis (L8046) is a removable superficial prosthesis which restores a portion of the face but which does not specifically involve the nose, orbit or ear.

A nasal septal prosthesis (L8047) is a removable prosthesis which occludes a hole in the nasal septum but does not include superficial nasal tissue.

Code V2623 describes an ocular prosthesis which is custom fabricated.

COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following coverage and payment rules.

A facial prosthesis is covered when there is loss or absence of facial tissue due to disease, trauma, surgery, or a congenital defect.

Adhesives, adhesive remover, and tape used in conjunction with a facial prosthesis are covered. Other skin care products related to the prosthesis, including but not limited to cosmetics, skin cream, cleansers, etc., are non-covered.

The following services and items are included in the allowance for a facial prosthesis and, therefore, are not separately billable to or payable by Medicare under the prosthetic device benefit:

- Evaluation of the patient
- Pre-operative planning
- Cost of materials
- Labor involved in the fabrication and fitting of the prosthesis
- Modifications to the prosthesis made at the time delivery of the prosthesis or within 90 days thereafter
- Repair due to normal wear or tear within 90 days of delivery

- Follow-up visits within 90 days of delivery of the prosthesis

Modifications to a prosthesis are separately payable when they occur more than 90 days after delivery of the prosthesis and they are required because of a change in the patient's condition.

Repairs are covered when there has been accidental damage or extensive wear to the prosthesis that can be repaired. If the expense for repairs exceeds the estimated expense for a replacement prosthesis, no payments can be made for the amount of the excess.

Follow-up visits which occur more than 90 days after delivery and which do not involve modification or repair of the prosthesis are non-covered services.

Replacement of a facial prosthesis is covered in cases of loss or irreparable damage or wear or when required because of a change in the patient's condition that cannot be accommodated by modification of the existing prosthesis. When replacement involves a new impression/moulage rather than use of a previous master model, the reason for the new impression/moulage must be clearly documented in the supplier's records and be available to the DMERC on request.

Claims for facial prostheses from nonphysicians provided in an office or nursing home setting are submitted to the DMERC. Claims for facial prostheses from physicians in these settings are submitted to the local carrier. Claims for facial prostheses provided in an outpatient hospital setting are submitted to the local intermediary. Facial prostheses provided in an inpatient hospital setting are included in the payment made to the hospital and therefore should not be submitted to the DMERC. Implanted prosthesis anchoring components should not be billed to the DMERC.

If an ocular prosthesis is dispensed to the patient as an integral part of a facial prosthesis, the ocular prosthesis component must be billed by the supplier of the facial prosthesis. (For information on ocular prostheses that are not part of orbital prostheses, refer to the medical policy on Eye Prostheses.)

CODING GUIDELINES

When a replacement prosthesis is fabricated starting with a new impression/moulage, the KM modifier should be added to the code. When a replacement prosthesis is fabricated using a previous master model, the KN modifier should be added to the code.

Covered modifications or repairs are billed using code L8049 for the labor components and Code K0448 for any materials used. Time reported using code L8049 should only be for laboratory modification/repair time and associated prosthetic evaluation used only for services after 90 days from the date of delivery of the prosthesis. Evaluation not associated with repair or modification is non-covered and should not be coded as L8049.

Adhesives, adhesive remover, and tape used in conjunction with a facial prosthesis should be billed using codes A4364, A4455, A4365, K0572 or K0573. The unit of service is specified for each code. For tape, one unit of service is 18 square inches. Therefore, a roll of tape 1/2" X 3 yds. would be 3 units; 1" x 3 yds. would be 6 units. Other skin care products related to the prosthesis should generally not be billed to the DMERC, but if they are billed at the beneficiary's request, code A9270 (non-covered item or service) should be used.

When a new ocular prosthesis component is provided as an integral part of an orbital, upper facial or hemi-facial prosthesis, it should be billed using code V2623 or V2629 on a separate claim line. When a replacement facial prosthesis utilizes an ocular component from the prior prosthesis, the ocular prosthesis code should not be billed.

If a facial prosthesis has a component which is used to attach it to a bone-anchored implant or to an internal prosthesis (e.g. maxillary obturator), that component should be billed separately using code L8048. This code should not be used for implanted prosthesis anchoring components.

Code L8048 is also used for a facial prosthesis that is not described by a specific code, L8040-L8047.

Code V2629 is used for an ocular prosthesis that is not custom fabricated (i.e. stock prosthesis).

When a prothesis is needed for adjacent facial regions, a single code must be used to bill for the item whenever possible. For example, if a defect involves the nose and orbit, this should be billed using the hemi-facial prosthesis code and not separate codes for the orbit and nose. This would apply even if the prosthesis is fabricated in two separate parts.

The right (RT) and left (LT) modifiers should be used with facial prosthesis codes when applicable. If bilateral prostheses using the same code are billed on the same date of service, the code should be entered on a single claims line using the LTRT modifiers and billed with 2 units of service.

Suppliers should refer to the Statistical Analysis DME Regional Carrier (SADMERC) web site or contact the SADMERC for guidance on the correct coding for these items.

DOCUMENTATION

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. § 1395l(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

An order for the initial prosthesis and/or related supplies which is signed and dated by the treating physician must be kept on file by the prosthetist/supplier. A separate physician order is not required for subsequent modifications, repairs or replacement of a facial prosthesis. A new order is required when different supplies are ordered.

When codes A4455, K0572, K0573, or A4365 are billed for supplies used in conjunction with a facial prosthesis, ICD-9 diagnosis code V43.89 should also be included on each claim.

A photograph of the prosthesis and a photograph of the patient without the prosthesis must be retained in the supplier's record and be available to the DMERC on request.

When code L8048 is used for a miscellaneous prosthesis or prosthetic component, the claim must be accompanied by a clear description and a drawing/copy of photograph of the item provided and the medical necessity.

When code V2629 is billed, the claim must be accompanied by a complete description of the item.

Claims for replacement, repair or modification of a facial prosthesis must include an explanation of the reason for the service.

When additional documentation is required, it should be entered in the HA0 record of an electronic claim or attached to a paper claim.

Refer to the Supplier Manual for more information on orders, medical records and supplier documentation.

EFFECTIVE DATE: Claims with dates of service on or after July 1, 2002.

This is a revision of a previously published policy.

General Information
Supplier Enrollment
Ombudsman Contacts
FAQs
Coverage
Certificates of Medical Necessity
Physician Information Sheets
SADMERC
Advisories
Manuals
Medical Policies
Fee Schedules
Forms
Appeals
Benefit Integrity
Learning & Education
Related Sites
DMERC Home
Providers Home

Manuals

<<BACK

Chapter 60 - Ostomy Supplies

View Attachments

Chapter 60 contains the medical policy for ostomy supplies. Click on View Attachments to download the entire chapter for viewing and printing in PDF format.

MEDICAL POLICY

SUBJECT: Ostomy Supplies

HCPCS CODES

The appearance of a code in this section does not necessarily indicate coverage.

A4331	Extension drainage tubing, any type, any length, with connector/adapter, for use with urinary leg bag or urostomy pouch, each
A4357	Bedside drainage bag, day or night, with or without anti-reflux device, with or without tube, each
A4361	Ostomy faceplate, each
A4362	Skin barrier; solid, 4 x 4 or equivalent, each
A4364	Adhesive, liquid or equal, any type, per ounce
A4365	Adhesive remover wipes, any type, per 50
A4367	Ostomy belt, each
A4369	Ostomy skin barrier, liquid (spray, brush, etc.), per oz.
A4371	Ostomy skin barrier, powder, per oz.
A4372	Ostomy skin barrier, solid 4 x 4 or equivalent, standard wear, with built-in convexity, each
A4373	Ostomy skin barrier, with flange (solid, flexible or accordion), standard wear, with built-in convexity, any size, each

A4375	Ostomy pouch, drainable, with faceplate attached, plastic, each
A4376	Ostomy pouch, drainable, with faceplate attached, rubber, each
A4377	Ostomy pouch, drainable, for use on faceplate, plastic, each
A4378	Ostomy pouch, drainable, for use on faceplate, rubber, each
A4379	Ostomy pouch, urinary, with faceplate attached, plastic, each
A4380	Ostomy pouch, urinary, with faceplate attached, rubber, each
A4381	Ostomy pouch, urinary, for use on faceplate, plastic, each
A4382	Ostomy pouch, urinary, for use on faceplate, heavy plastic, each
A4383	Ostomy pouch, urinary, for use on faceplate, rubber, each
A4384	Ostomy faceplate equivalent, silicone ring, each
A4385	Ostomy skin barrier, solid 4 x 4 or equivalent, extended wear, without built-in convexity, each
A4387	Ostomy pouch closed, with standard wear barrier attached, with built-in convexity (1 piece), each
A4388	Ostomy pouch, drainable, with extended wear barrier attached, without built-in convexity (1 piece)
A4389	Ostomy pouch, drainable, with standard wear barrier attached, with built-in convexity (1 piece), each
A4390	Ostomy pouch, drainable, with extended wear barrier attached, with built-in convexity (1 piece), each
A4391	Ostomy pouch, urinary, with extended wear barrier attached, without built-in convexity (1 piece), each
A4392	Ostomy pouch, urinary, with standard wear barrier attached, with built-in convexity (1 piece), each
A4393	Ostomy pouch, urinary, with extended wear barrier attached, with built-in convexity (1 piece), each
A4394	Ostomy deodorant for use in ostomy pouch, liquid, per fluid ounce
A4395	Ostomy deodorant for use in ostomy pouch, solid, per tablet
A4396	Ostomy belt with peristomal hernia support
A4397	Irrigation supply; sleeve, each
A4398	Ostomy irrigation supply; bag, each
A4399	Ostomy irrigation supply; cone/catheter, including brush
A4402	Lubricant, per ounce
A4404	Ostomy ring, each
A4421	Ostomy supply; miscellaneous
A4455	Adhesive remover or solvent (for tape, cement or other adhesive), per ounce
A5051	Pouch, closed; with barrier attached (1 piece)

A5052	Pouch, closed; without barrier attached (1 piece)
A5053	Pouch, closed; for use on faceplate
A5054	Pouch, closed; for use on barrier with flange (2 piece)
A5055	Stoma cap
A5062	Pouch, drainable; without barrier attached (1 piece)
A5063	Pouch, drainable; for use on barrier with flange (2 piece system)
A5071	Pouch, urinary; with barrier attached (1 piece)
A5072	Pouch, urinary; without barrier attached (1 piece)
A5073	Pouch, urinary; for use on barrier with flange (2 piece)
A5081	Continent device; plug for continent stoma
A5082	Continent device; catheter for continent stoma
A5093	Ostomy accessory; convex insert
A5102	Bedside drainage bottle with or without tubing, rigid or expandable, each
A5119	Skin barrier; wipes, box per 50
A5121	Skin barrier; solid, 6 x 6 or equivalent, each
A5122	Skin barrier; solid, 8 x 8 or equivalent, each
A5126	Adhesive or non-adhesive; disc or foam pad
A5131 A6216	Appliance cleaner, incontinence and ostomy appliances, per 16 oz. Gauze, non-impregnated, non-sterile, pad size 16 sq. in. or less, without adhesive border, each dressing.
A9270 K0561	Non-covered item or service Ostomy skin barrier, non-pectin based, paste, per ounce
K0562	Ostomy skin barrier, pectin-based, paste, per ounce
K0563	Ostomy skin barrier, with flange (solid, flexible, or accordion), extended wear, with built-in convexity, 4 x 4 inches or smaller, each
K0564	Ostomy skin barrier, with flange (solid, flexible, or accordion), extended wear, with built-in convexity, larger than 4 x 4 inches, each
K0565	Ostomy skin barrier, with flange (solid, flexible, or accordion), extended wear, without built-in convexity, 4 x 4 inches or smaller, each
K0566	Ostomy skin barrier, with flange (solid, flexible, or accordion), extended wear, without built-in convexity, larger than 4 x 4 inches, each
K0567	Ostomy pouch, drainable, with karaya based barrier attached,

	without built-in convexity, 1 piece, each
K0568	Ostomy pouch, drainable, with standard wear barrier attached, without built-in convexity, (1 piece), each
K0569	Ostomy pouch, drainable, high output, for use on a barrier with flange (2 piece system), each
K0570	Ostomy skin barrier, with flange (solid, flexible, or accordion), without built-in convexity, 4 x 4 inches or smaller, each
K0571	Ostomy skin barrier, with flange (solid, flexible, or accordion), without built-in convexity, larger than 4 x 4 inches, each
K0572	Tape, non-waterproof, per 18 square inches
K0573	Tape, waterproof, per 18 square inches
K0574	Addition to ostomy pouch, filter, integral or added separately to pouch, each
K0575	Addition to ostomy pouch, rustle-free material, per pouch
K0576	Addition to ostomy pouch, friction and irritant-reducing, absorbent, interface layer (comfort panel), per pouch
K0577	Addition to ostomy pouch, odor barrier, incorporated into pouch laminate, per pouch
K0578	Addition to ostomy pouch, faucet-type tap with valve for draining urinary pouch, each
K0579	Addition to ostomy pouch, absorbent material (sheet/pad/crystal packet) to thicken liquid stomal output, for use in pouch, each
K0580	Addition to ostomy pouch, flange locking mechanism, each

BENEFIT CATEGORY: Prosthetic Devices

DEFINITIONS

Barriers

A solid barrier (wafer) is an interface between the patient's skin and the pouching system, has measurable thickness and has an adhesive property. Barriers may be integrated into a "1 piece" pouch, they may be manufactured with a flange and be part of a "2 piece" pouch system (skin barrier with flange, e.g., K0570), or they may be used independently (e.g., A4362), usually with a pouch that does not have its own integral skin barrier. When barriers are used as part of a "1 piece" drainable pouch, they may be either pectin-based (e.g., K0568), or karaya-based (e.g., K0567). An extended wear barrier (e.g., K0565) is a pectin-based barrier with special additives which achieve a stronger adhesive seal, resist breakdown by urine or bowel effluent, permit longer wear times between changes, and normal wear times for those who cannot achieve them with standard barriers. There are distinct codes for extended wear compared to standard wear barriers.

A barrier with built in convexity (e.g., K0563) is one in which an outward curve is usually achieved with plastic embedded in the barrier, allowing

better protrusion of the stoma and adherence to the skin. There are distinct codes for barriers with built-in convexity compared to flat barriers.

Ostomy skin barriers greater than 4x4 inches (K0564, K0566, K0571) refer to the size of the skin barriers themselves, and not to the area of any surrounding tape.

Faceplates

A faceplate is a solid interface between the patient's skin and the pouch. It is usually made of plastic, rubber or encased metal. It does not have an adhesive property and there is no pectin-based or karaya material that is an integral part of a faceplate. It can be taken off the skin and reattached repeatedly. It is held on by means of a separate adhesive and/or an elastic belt. The clips for attaching the belt are usually a part of the faceplate. There is no coding distinction between flat and convex faceplates.

Pouches

A pouch is a device for collecting stomal output. A pouch for collecting bowel effluent may be either "drainable" with an opening at the bottom through which the fecal contents are emptied, or "closed" with a sealed bottom and no outlet. A "urinary" pouch normally incorporates anti-reflux devices and a tap or spigot to empty the urine contents.

A pouch "with barrier attached" is one type of "1 piece" system in which a solid barrier is part of the pouch. There are distinct codes for 1 piece pouches with convex barriers and extended wear barriers (see "Barriers").

A pouch "without barrier attached" is a pouch with or without a thin adhesive coating that is applied either directly to the skin or to a separate barrier. It is also described as a "1 piece" system.

A pouch which is part of a "2 piece" system has a flange which enables it to be coupled to a skin barrier with flange.

A pouch "with faceplate attached" or "for use on a faceplate" is generally rubber or heavy plastic. It is drainable, cleanable, and reusable for periods of weeks to months, depending on the product.

A "high output" pouch (K0569) has a capacity of greater than or equal to 0.75 liters, an anti-reflux valve, a large bore solid spout with cap or plug and is part of a 2 piece system.

Add on Features to Pouches

Filters (K0574) allow venting of gas trapped in the ostomy pouch. They may also include materials such as charcoal to deodorize the vented gas. Filters may be incorporated in the pouch, inserted into a venting ring on the pouch, or attached to the pouch exterior.

Rustle-free material (K0575) reduces the crackling noise produced by pouch materials with bodily movement.

Friction and irritant - reducing, absorbent interface layer (comfort panel) (K0576) is a soft material layer on the body side of the pouch that reduces skin irritation, sticking and sweating that would otherwise result from direct contact of the pouch with the skin.

An odor barrier (K0577) is a film layer (e.g., polyvinyl dichloride) incorporated into the pouch, which serves to retain excrement odor within the pouch. It is separate from any odor absorbing material contained in a pouch filter (K0574).

A faucet-type tap (K0578) with a valve for draining urinary pouches (A4391, A4392, A4393, A5071, A5072, A5073) is distinguished from plugs, caps, fold up or clip type drainage closures.

Absorbent material (K0579) that is added to the ostomy pouch may come as sheets, pads or crystals.

Code (K0580) describes a lever type flange locking mechanism. It differs from simple push on pouch securing mechanisms. The mechanism may be incorporated either in the pouch flange or skin barrier flange.

Pastes

A paste is used as a protective layer and sealant beneath ostomy appliances, and is applied directly on the skin. It may be primarily pectin based (K0562), or non-pectin based, e.g., karaya (K0561).

COVERAGE AND PAYMENT RULES

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following coverage and payment rules.

Ostomy supplies are covered for use on patients with a surgically created opening (stoma) to divert urine or fecal contents outside the body. Ostomy supplies are appropriately used for colostomies V44.3, V55.3, ileostomies V44.2, V55.2 or urinary ostomies V44.6, V55.6. Use for other conditions will be denied as medically unnecessary.

When supplied with a covered ostomy pouch, codes K0574 - K0580 are paid separately and in addition to the ostomy pouch codes for which these K

codes represent add-on features.

The quantity of ostomy supplies needed by a patient is determined to a great extent by the type of ostomy, its location, its construction, and the condition of the skin surface surrounding the stoma. There will be variation according to individual patient need and their needs may vary over time. The table below lists the maximum number of items/units of service that are usually medically necessary. The actual quantity needed by a particular patient may be more or less than the amount listed depending on the factors that affect the frequency of barrier and pouch change. The medical necessity for use of a greater quantity of supplies than the amounts listed must be well documented in the patient's medical record and may be requested by the DMERC.

(**Note:** The number listed in the table refers to the number of units. For example, for A5119, 3 per six months represents 150 wipes since the unit of service for A5119 is 50 wipes.

Usual Maximum Quantity of Supplies					
Code	**#/month**	**#/6 month**	**Code**	**#/month**	**#/6 month**
A4357	2		A5071	20	
A4361		3	A5072	20	
A4362	20		A5073	20	
A4364	4		A5081	31	
A4367	1		A5082	1	
A4369	2		A5093	10	
A4371		10	A5102		2
A4377	10		A5119		3
A4381	10		A5121	20	
A4397	4		A5122	20	
A4398		2	A5126	20	
A4399		2	A5131	1	
A4402	4		A6216	60	
A4404	10		K0561	4	
A4455		16	K0562	4	
A5051	60		K0567	20	
A5052	60		K0568	20	
A5053	60		K0570	20	
A5054	60		K0571	20	
A5055	31		K0572	40	

A5062	20		K0573	40	
A5063	20				

Provision of ostomy supplies should be limited to a one-month supply for a patient in a nursing facility and a 3-month supply for a patient at home.

When a liquid barrier is necessary, either liquid or spray (A4369) or individual wipes (A5119) is appropriate. The use of both is not medically necessary.

Patients with continent stomas may use the following means to prevent/manage drainage: stoma cap (A5055), stoma plug (A5081) or gauze pads (A6216). No more than one type of supply would be medically necessary on a given day.

Patients with urinary ostomies may use either a bag (A4357) or bottle (A5102) for drainage at night. It is not medically necessary to have both.

A pouch cover should be coded A9270 and will be denied as a non-covered item.

CODING GUIDELINES

The following codes are not valid for submission to the DMERC:

- A4368 Ostomy filter, any type, each
- A4370 Ostomy skin barrier, paste, per oz.
- A4374 Ostomy skin barrier, with flange (solid, flexible or accordion), extended wear, with built-in convexity, any size, each
- A4386 Ostomy skin barrier, with flange (solid, flexible or accordion), extended wear, without built-in convexity, any size, each
- A5061 Pouch, drainable; with barrier attached (1 piece)
- A5123 Skin barrier; with flange (solid, flexible or accordion), any size, each
- A6265 Tape, all types, per 18 square inches

When supplied with a covered ostomy pouch, codes K0574 - K0580 should be billed on separate claim lines, in addition to the ostomy pouch code, when they represent additional features of that pouch..

For codes K0575, K0576, K0577, K0578, K0580, suppliers may bill for only one unit of each code per pouch.

Code A4400 (Ostomy irrigation set), for an irrigation kit, is not valid for claims submitted to the DMERC. If an irrigation kit is supplied, the individual components should be billed using individual codes, A4367,

A4397, A4398, and A4399.

The following table lists codes for faceplate systems. When supplying a pouch with faceplate attached (Column I) a claim may not be made for a component product from Column II provided at the same time.

Column I	Column II
A4375	A4361, A4377
A4376	A4361, A4378
A4379	A4361, A4381, A4382
A4380	A4361, A4383

Suppliers should contact the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) for guidance on the correct coding of these devices.

DOCUMENTATION

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. § 1395l(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

An order for the ostomy supplies which has been signed and dated by the treating physician must be kept on file by the supplier. The order must include the type(s) of supplies ordered and the approximate quantity to be used per unit of time. An ICD-9 diagnosis code describing the type of ostomy (V44.2, V44.3, V44.6, V55.2, V55.3, or V55.6) must be included on the initial order to a supplier. A new order is required if there is an increase in the quantity of the supply used per month and/or the type of supply used. . The add-on codes (K0574-K0580) do not need to be specifically listed on the physician's order.

When supplies used are greater than the usual maximum quantity listed in the Coverage and Payment Rules, there must be adequate documentation in the patient's medical records corroborating the medical necessity of this amount. The DMERC may request copies of the patient's medical records that corroborate the order and any additional documentation that pertains to the medical necessity of items and quantities billed.

The supplier must enter the diagnosis code for the ostomy on each claim submitted for ostomy supplies. If there is more than one ostomy, enter the appropriate codes.

Refer to the Supplier Manual for more information on orders, medical records, and supplier documentation.

EFFECTIVE DATE: Claims with dates of service on or after July 1, 2002.

This is a revision to a previously published policy.

≪BACK

Region C DMEPOS Supplier Manual (updated through Autumn 2002)
....Change of Address Notification Form
....Contents
....Index
....Part I - General Information
.....Chapter 1 - Beneficiary Eligibility & Supplier Responsibility
.....Chapter 2 - Jurisdiction
.....Chapter 3 - National Supplier Clearinghouse
.....Chapter 4 - Statistical Analysis DMERC
.....Chapter 5 - Claims Filing
.....Chapter 6 - Documentation Requirements
.....Chapter 7 - Advance Beneficiary Notice
.....Chapter 8 - Durable Medical Equipment
.....Chapter 9 - Pricing
.....Chapter 10 - Claim Payment
.....Chapter 11 - Medicare Assignment Agreement
.....Chapter 12 - Medicare as Secondary Payer
.....Chapter 13 - Multifunctional Teams & Professional Relations
.....Chapter 14 - Appeals Process
.....Chapter 15 - Fraud & Abuse
.....Chapter 16 - Regionalization of Medical Policy
.....Chapter 17 - Internet Web Sites
....Part II - Medical Policies
.....Chapter 18 - Medical Policy
.....Chapter 19-A Intrapulmonary Percussive Ventilation System
.....Chapter 19 - Oxygen
.....Chapter 20 - Nebulizers
.....Chapter 21 - Canes and Crutches
.....Chapter 22 - Walkers
.....Chapter 23 - Commodes
.....Chapter 24 - Manual Wheelchair Base
.....Chapter 25 - Motorized/Power Wheelchair Base
.....Chapter 26 - Wheelchair Options/Accessories
.....Chapter 27 - Power Operated Vehicles (POVs)
.....Chapter 28 - Seat Lift Mechanisms
.....Chapter 29 - Patient Lifts
.....Chapter 30 - Hospital Beds and Accessories
.....Chapter 31 - Reserved for Future Use
.....Chapter 32 - Reserved for Future Use
.....Chapter 33 - Reserved for Future Use
.....Chapter 34 - Reserved for Future Use

MEDICAL POLICY

SUBJECT: Ostomy Supplies

HCPCS CODES

The appearance of a code in this section does not necessarily indicate coverage.

A4331 Extension drainage tubing, any type, any length, with connector/adapter, for use with urinary leg bag or urostomy pouch, each
A4357 Bedside drainage bag, day or night, with or without anti-reflux device, with or without tube, each
A4361 Ostomy faceplate, each
A4362 Skin barrier; solid, 4 x 4 or equivalent, each
A4364 Adhesive, liquid or equal, any type, per ounce
A4365 Adhesive remover wipes, any type, per 50
A4367 Ostomy belt, each

A4369 Ostomy skin barrier, liquid (spray, brush, etc.), per oz.

A4371 Ostomy skin barrier, powder, per oz.
A4372 Ostomy skin barrier, solid 4 x 4 or equivalent, standard wear, with built-in convexity, each
A4373 Ostomy skin barrier, with flange (solid, flexible or accordion), standard wear, with built-in convexity, any size, each

A4375 Ostomy pouch, drainable, with faceplate attached, plastic, each
A4376 Ostomy pouch, drainable, with faceplate attached, rubber, each
A4377 Ostomy pouch, drainable, for use on faceplate, plastic, each
A4378 Ostomy pouch, drainable, for use on faceplate, rubber, each
A4379 Ostomy pouch, urinary, with faceplate attached, plastic, each
A4380 Ostomy pouch, urinary, with faceplate attached, rubber, each
A4381 Ostomy pouch, urinary, for use on faceplate, plastic, each
A4382 Ostomy pouch, urinary, for use on faceplate, heavy plastic, each
A4383 Ostomy pouch, urinary, for use on faceplate, rubber, each
A4384 Ostomy faceplate equivalent, silicone ring, each
A4385 Ostomy skin barrier, solid 4 x 4 or equivalent, extended wear, without built-in convexity, each

A4387 Ostomy pouch closed, with standard wear barrier attached, with built-in convexity (1 piece), each

A4388 Ostomy pouch, drainable, with extended wear barrier attached, without built-in convexity (1 piece)
A4389 Ostomy pouch, drainable, with standard wear barrier attached, with built-in convexity (1 piece), each
A4390 Ostomy pouch, drainable, with extended wear barrier attached, with built-in convexity (1 piece), each
A4391 Ostomy pouch, urinary, with extended wear barrier attached, without built-in convexity (1 piece), each

A4392	Ostomy pouch, urinary, with standard wear barrier attached, with built-in convexity (1 piece), each
A4393	Ostomy pouch, urinary, with extended wear barrier attached, with built-in convexity (1 piece), each
A4394	Ostomy deodorant for use in ostomy pouch, liquid, per fluid ounce
A4395	Ostomy deodorant for use in ostomy pouch, solid, per tablet
A4396	Ostomy belt with peristomal hernia support
A4397	Irrigation supply; sleeve, each
A4398	Ostomy irrigation supply; bag, each
A4399	Ostomy irrigation supply; cone/catheter, including brush
A4402	Lubricant, per ounce
A4404	Ostomy ring, each
A4421	Ostomy supply; miscellaneous
A4455	Adhesive remover or solvent (for tape, cement or other adhesive), per ounce
A5051	Pouch, closed; with barrier attached (1 piece)
A5052	Pouch, closed; without barrier attached (1 piece)
A5053	Pouch, closed; for use on faceplate
A5054	Pouch, closed; for use on barrier with flange (2 piece)
A5055	Stoma cap
A5062	Pouch, drainable; without barrier attached (1 piece)
A5063	Pouch, drainable; for use on barrier with flange (2 piece system)
5071	Pouch, urinary; with barrier attached (1 piece)
A5072	Pouch, urinary; without barrier attached (1 piece)
A5073	Pouch, urinary; for use on barrier with flange (2 piece)
A5081	Continent device; plug for continent stoma
A5082	Continent device; catheter for continent stoma
A5093	Ostomy accessory; convex insert
A5102	Bedside drainage bottle with or without tubing, rigid or expandable, each
A5119	Skin barrier; wipes, box per 50
A5121	Skin barrier; solid, 6 x 6 or equivalent, each
A5122	Skin barrier; solid, 8 x 8 or equivalent, each
A5126	Adhesive or non-adhesive; disc or foam pad
A5131	Appliance cleaner, incontinence and ostomy appliances, per 16 oz.
A6216	Gauze, non-impregnated, non-sterile, pad size 16 sq. in. or less, without adhesive border, each dressing.
A9270	Non-covered item or service
K0561	Ostomy skin barrier, non-pectin based, paste, per ounce
K0562	Ostomy skin barrier, pectin-based, paste, per ounce
K0563	Ostomy skin barrier, with flange (solid, flexible, or accordion), extended wear, with built-in convexity, 4 x 4 inches or smaller, each
564	Ostomy skin barrier, with flange (solid, flexible, or accordion), extended wear, with built-in convexity, larger than 4 x 4 inches, each

K0565	Ostomy skin barrier, with flange (solid, flexible, or accordion), extended wear, without built-in convexity, 4 x 4 inches or smaller, each
K0566	Ostomy skin barrier, with flange (solid, flexible, or accordion), extended wear, without built-in convexity, larger than 4 x 4 inches, each
K0567	Ostomy pouch, drainable, with karaya based barrier attached, without built-in convexity, 1 piece, each
K0568	Ostomy pouch, drainable, with standard wear barrier attached, without built-in convexity, (1 piece), each
K0569	Ostomy pouch, drainable, high output, for use on a barrier with flange (2 piece system), each
K0570	Ostomy skin barrier, with flange (solid, flexible, or accordion), without built-in convexity, 4 x 4 inches or smaller, each
K0571	Ostomy skin barrier, with flange (solid, flexible, or accordion), without built-in convexity, larger than 4 x 4 inches, each
K0572	Tape, non-waterproof, per 18 square inches
K0573	Tape, waterproof, per 18 square inches
K0574	Addition to ostomy pouch, filter, integral or added separately to pouch, each
K0575	Addition to ostomy pouch, rustle-free material, per pouch
K0576	Addition to ostomy pouch, friction and irritant-reducing, absorbent, interface layer (comfort panel), per pouch
K0577	Addition to ostomy pouch, odor barrier, incorporated into pouch laminate, per pouch
K0578	Addition to ostomy pouch, faucet-type tap with valve for draining urinary pouch, each
K0579	Addition to ostomy pouch, absorbent material (sheet/pad/crystal packet) to thicken liquid stomal output, for use in pouch, each
K0580	Addition to ostomy pouch, flange locking mechanism, each

BENEFIT CATEGORY: Prosthetic Devices

DEFINITIONS

Barriers

A solid barrier (wafer) is an interface between the patient's skin and the pouching system, has measurable thickness and has an adhesive property. Barriers may be integrated into a "1 piece" pouch, they may be manufactured with a flange and be part of a "2 piece" pouch system (skin barrier with flange, e.g., K0570), or they may be used independently (e.g., A4362), usually with a pouch that does not have its own integral skin barrier. When barriers are used as part of a "1 piece" drainable pouch, they may be either pectin-based (e.g., K0568), or karaya-based (e.g., K0567). An extended wear barrier (e.g., K0565) is a pectin-based barrier with special additives which achieve a stronger adhesive seal, resist breakdown by urine or bowel effluent, permit longer wear times between changes, and normal wear times for those who cannot achieve them with standard barriers. There are distinct codes for extended wear compared to standard wear barriers.

A barrier with built in convexity (e.g., K0563) is one in which an outward curve is usually achieved with plastic embedded in the barrier, allowing better protrusion of the stoma and adherence to the skin. There are distinct codes for barriers with built-in convexity compared to flat barriers.

Ostomy skin barriers greater than 4x4 inches (K0564, K0566, K0571) refer to the size of the skin barriers themselves, and not to the area of any surrounding tape.

Faceplates

A faceplate is a solid interface between the patient's skin and the pouch. It is usually made of plastic, rubber or encased metal. It does not have an adhesive property and there is no pectin-based or karaya material that is an integral part of a faceplate. It can be taken off the skin and reattached repeatedly. It is held on by means of a separate adhesive and/or an elastic belt. The clips for attaching the belt are usually a part of the faceplate. There is no coding distinction between flat and convex faceplates.

Pouches

A pouch is a device for collecting stomal output. A pouch for collecting bowel effluent may be either "drainable" with an opening at the bottom through which the fecal contents are emptied, or "closed" with a sealed bottom and no outlet. A "urinary" pouch normally incorporates anti-reflux devices and a tap or spigot to empty the urine contents.

A pouch "with barrier attached" is one type of "1 piece" system in which a solid barrier is part of the pouch. There are distinct codes for 1 piece pouches with convex barriers and extended wear barriers (see "Barriers").

A pouch "without barrier attached" is a pouch with or without a thin adhesive coating that is applied either directly to the skin or to a separate barrier. It is also described as a "1 piece" system.

A pouch which is part of a "2 piece" system has a flange which enables it to be coupled to a skin barrier with flange.

A pouch "with faceplate attached" or "for use on a faceplate" is generally rubber or heavy plastic. It is drainable, cleanable, and reusable for periods of weeks to months, depending on the product.

A "high output" pouch (K0569) has a capacity of greater than or equal to 0.75 liters, an anti-reflux valve, a large bore solid spout with cap or plug and is part of a 2 piece system.

Add on Features to Pouches

Filters (K0574) allow venting of gas trapped in the ostomy pouch. They may also include materials such as charcoal to deodorize the vented gas. Filters may be incorporated in the pouch, inserted into a venting ring on the pouch, or attached to the pouch exterior.

Rustle-free material (K0575) reduces the crackling noise produced by pouch materials with bodily movement.

Friction and irritant - reducing, absorbent interface layer (comfort panel) (K0576) is a soft material layer on the body side of the pouch that reduces skin irritation, sticking and sweating that would otherwise result from direct contact of the pouch with the skin.

An odor barrier (K0577) is a film layer (e.g., polyvinyl dichloride) incorporated into the pouch, which serves to retain excrement odor within the pouch. It is separate from any odor absorbing material contained in a pouch filter (K0574).

A faucet-type tap (K0578) with a valve for draining urinary pouches (A4391, A4392, A4393, A5071, A5072, A5073) is distinguished from plugs, caps, fold up or clip type drainage closures.

Absorbent material (K0579) that is added to the ostomy pouch may come as sheets, pads or crystals.

Code (K0580) describes a lever type flange locking mechanism. It differs from simple push on pouch securing mechanisms. The mechanism may be incorporated either in the pouch flange or skin barrier flange.

Pastes

A paste is used as a protective layer and sealant beneath ostomy appliances, and is applied directly on the skin. It may be primarily pectin based (K0562), or non-pectin based, e.g., karaya (K0561).

COVERAGE AND PAYMENT RULES

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following coverage and payment rules.

Ostomy supplies are covered for use on patients with a surgically created opening (stoma) to divert urine or fecal contents outside the body. Ostomy supplies are appropriately used for colostomies V44.3, V55.3, ileostomies V44.2, V55.2 or urinary ostomies V44.6, V55.6. Use for other conditions will be denied as medically unnecessary.

When supplied with a covered ostomy pouch, codes K0574 - K0580 are paid separately and in addition to the ostomy pouch codes for which these K codes represent add-on features.

The quantity of ostomy supplies needed by a patient is determined to a great extent by the type of ostomy, its location, its construction, and the condition of the skin surface surrounding the stoma. There will be variation according to individual patient need and their needs may vary over time. The table below lists the maximum number of items/units of service that are usually medically necessary. The actual quantity needed by a particular patient may be more or less than the amount listed depending on the factors that affect the frequency of barrier and pouch change. The medical necessity for use of a greater quantity of supplies than the amounts listed must be well documented in the patient's medical record and may be requested by the DMERC.

(Note: The number listed in the table refers to the number of units. For example, for A5119, 3 per six months represents 150 wipes since the unit of service for A5119 is 50 wipes.

USUAL MAXIMUM QUANTITY OF SUPPLIES					
CODE	#/MONTH	#/6 MONTH	CODE	#/MONTH	#/6 MONTH
A4357	2		A5071	20	
A4361		3	A5072	20	
A4362	20		A5073	20	
A4364	4		A5081	31	
A4367	1		A5082	1	
A4369	2		A5093	10	
A4371		10	A5102		2
A4377	10		A5119		3
A4381	10		A5121	20	
A4397	4		A5122	20	
A4398		2	A5126	20	
A4399		2	A5131	1	

USUAL MAXIMUM QUANTITY OF SUPPLIES					
CODE	#/MONTH	#/6 MONTH	CODE	#/MONTH	#/6 MONTH
A4402	4		A6216	60	
A4404	10		K0561	4	
A4455		16	K0562	4	
A5051	60		K0567	20	
A5052	60		K0568	20	
A5053	60		K0570	20	
A5054	60		K0571	20	
A5055	31		K0572	40	
A5062	20		K0573	40	
A5063	20				

Provision of ostomy supplies should be limited to a one month supply for a patient in a nursing facility and a 3 month supply for a patient at home.

When a liquid barrier is necessary, either liquid or spray (A4369) or individual wipes (A5119) is appropriate. The use of both is not medically necessary.

Patients with continent stomas may use the following means to prevent/manage drainage: stoma cap (A5055), stoma plug (A5081) or gauze pads (A6216). No more than one type of supply would be medically necessary on a given day.

Patients with urinary ostomies may use either a bag (A4357) or bottle (A5102) for drainage at night. It is not medically necessary to have both.

A pouch cover should be coded A9270 and will be denied as a non-covered item.

CODING GUIDELINES

The following codes are not valid for submission to the DMERC:

- A4368 Ostomy filter, any type, each
- A4370 Ostomy skin barrier, paste, per oz.
- A4374 Ostomy skin barrier, with flange (solid, flexible or accordion), extended wear, with built-in convexity, any size, each
- A4386 Ostomy skin barrier, with flange (solid, flexible or accordion), extended wear, without built-in convexity, any size, each
- A5061 Pouch, drainable, with barrier attached (1 piece)
- A5123 Skin barrier, with flange (solid, flexible or accordion), any size, each
- A6265 Tape, all types, per 18 square inches

When supplied with a covered ostomy pouch, codes K0574 - K0580 should be billed on separate claim lines, in addition to the ostomy pouch code, when they represent additional features of that pouch.

For codes K0575, K0576, K0577, K0578, K0580, suppliers may bill for only one unit of each code per pouch.

Code A4400 (Ostomy irrigation set), for an irrigation kit, is not valid for claims submitted to the DMERC. If an irrigation kit is supplied, the individual components should be billed using individual codes, A4367, A4397, A4398, and A4399.

The following table lists codes for faceplate systems. When supplying a pouch with faceplate attached (Column I) a claim may not be made for a component product from Column II provided at the same time.

COLUMN I	COLUMN II
A4375	A4361, A4377
A4376	A4361, A4378
A4379	A4361, A4381, A4382
A4380	A4361, A4383

Suppliers should contact the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) for guidance on the correct coding of these devices.

DOCUMENTATION

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. § 1395l(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

An order for the ostomy supplies which has been signed and dated by the treating physician must be kept on file by the supplier. The order must include the type(s) of supplies ordered and the approximate quantity to be used per unit of time. An ICD-9 diagnosis code describing the type of ostomy (V44.2, V44.3, V44.6, V55.2, V55.3, or V55.6) must be included on the initial order to a supplier. A new order is required if there is an increase in the quantity of the supply used per month and/or the type of supply used. . The add-on codes (K0574 K0580) do not need to be specifically listed on the physician's order.

When supplies used are greater than the usual maximum quantity listed in the Coverage and Payment Rules, there must be adequate documentation in the patient's medical records corroborating the medical necessity of this amount. The DMERC may request copies of the patient's medical records that corroborate the order and any additional documentation that pertains to the medical necessity of items and quantities billed.

The supplier must enter the diagnosis code for the ostomy on each claim submitted for ostomy supplies. If there is more than one ostomy, enter the appropriate codes.

Refer to the Supplier Manual for more information on orders, medical records, and supplier documentation.

EFFECTIVE DATE: Claims with dates of service on or after July 1, 2002.

This is a revision to a previously published policy.

General Information
Supplier Enrollment
Ombudsman Contacts
FAQs
Coverage
Certificates of Medical Necessity
Physician Information Sheets
SADMERC
Advisories
Manuals
Medical Policies
Fee Schedules
Forms
Appeals
Benefit Integrity
Learning & Education
Related Sites
DMERC Home
Providers Home

Manuals

<<BACK

Chapter 61-A - Negative Pressure Wound Therapy Pumps

View Attachments

Chapter 61-A contains the medical policy for negative pressure wound therapy pumps. Click on View Attachments to download the entire chapter for viewing and printing in PDF format.

MEDICAL POLICY

SUBJECT: Negative Pressure Wound Therapy Pumps

HCPCS CODES:

The appearance of a code in this section does not necessarily indicate coverage.

EQUIPMENT

K0538 Negative pressure wound therapy electrical pump, stationary or portable

SUPPLIES:

K0539 Dressing set for negative pressure wound therapy electrical pump, stationary or portable, each

K0540 Canister set for negative pressure wound therapy electrical pump, stationary or portable, each

HCPCS MODIFIER:

KX: Specific required documentation on file.

BENEFIT CATEGORY: Durable Medical Equipment

DEFINITIONS

Negative pressure wound therapy (NPWT) is the controlled application of subatmospheric pressure to a wound using an electrical pump (described in the definition of HCPCS code K0538) to intermittently or continuously convey subatmospheric pressure through connecting tubing to a specialized wound dressing (described in the definition of HCPCS code K0539) which includes a resilient, open-cell foam surface dressing, sealed with an occlusive dressing that is meant to contain the subatmospheric pressure at the wound site and thereby promote wound healing. Drainage from the wound is collected in a canister (described in the definition of HCPCS code K0540).

HCPCS code **K0538** describes a stationary or portable NPWT electrical pump which provides controlled subatmospheric pressure that is designed for use with NPWT dressings, (K0539) to promote wound healing. Such an NPWT pump is capable of being selectively switched between continuous and intermittent modes of operation and is controllable to adjust the degree of subatmospheric pressure conveyed to the wound in a range from 25 to $\geq$ 200 mm Hg subatmospheric pressure. The pump is capable of sounding an audible alarm when desired pressures are not being achieved (that is, where there is a leak in the dressing seal) and when its wound drainage canister (K0540) is full. The pump is designed to fill the canister to full capacity.

HCPCS code **K0539** describes a dressing set which is used in conjunction with a stationary or portable NPWT pump (K0538), and contains all necessary components, including but not limited to a resilient, open-cell foam surface dressing, drainage tubing, and an occlusive dressing which creates a seal around the wound site for maintaining subatmospheric pressure at the wound.

HCPCS code **K0540** describes a canister set which is used in conjunction with a stationary or portable NPWT pump (K0538) and contains all necessary components, including but not limited to a container, to collect wound exudate. Canisters may be various sizes to accommodate stationary or portable NPWT pumps.

A licensed health care professional, for the purposes of this policy, may be a physician, physician's assistant (PA), registered nurse (RN), licensed practical nurse (LPN), or physical therapist (PT). The practitioner should be licensed to assess wounds and/or administer wound care within the state where the beneficiary is receiving NPWT.

Lack of improvement of a wound, as used within this policy, is defined as a lack of progress in quantitative measurements of wound characteristics including wound length and width (surface area), or depth measured serially and documented, over a specified time interval. Wound healing is defined as improvement occurring in either surface area or depth of the wound.

The staging of pressure ulcers used in this policy is as follows:

Stage I	Observable pressure related alteration of intact skin whose indicators as compared to the adjacent or opposite area on the body may include changes in one of more of the following: skin temperature (warmth or coolness), tissue consistency (firm or boggy feel) and/or sensation (pain, itching). The ulcer appears as a defined area of persistent redness in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue, or purple hues.
Stage II	Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater.
Stage III	Full thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.
Stage IV	Full thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g., tendon, joint capsule). Undermining and sinus tracts also may be associated with Stage IV pressure ulcers.

COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must: 1) be eligible for a defined Medicare Benefit Category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following coverage and payment rules.

Equipment:

Initial Coverage:

An NPWT pump and supplies are covered when either criterion **A** or **B** is met:

A) Ulcers and Wounds in the Home Setting:

The patient has a chronic Stage III or IV pressure ulcer, neuropathic (for example, diabetic) ulcer, venous or arterial insufficiency ulcer, or a chronic (being present for at least 30 days) ulcer of mixed etiology. A complete wound therapy program described by criterion **1** and criteria **2**, **3**, or **4**, as applicable depending on the type of wound, should have been tried or considered and ruled out prior to application of NPWT.

1) For all ulcers or wounds, the following components of a wound therapy program must include a minimum of all of the following general measures,

which should be addressed, applied, or considered and ruled out prior to application of NPWT:
a) Documentation in the patient's medical record of evaluation, care, and wound measurements by a licensed medical professional, and
b) Application of dressings to maintain a moist wound environment, and
c) Debridement of necrotic tissue if present, and
d) Evaluation of and provision for adequate nutritional status.
2) For Stage III or IV pressure ulcers:
a) The patient has been appropriately turned and positioned, and
b) The patient has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis (see DMERC medical policy on support surfaces), (a group 2 or 3 support surface is not required if the ulcer is not on the trunk or pelvis) and
c) The patient's moisture and incontinence have been appropriately changed.

3) For neuropathic (for example, diabetic) ulcers:
a) The patient has been on a comprehensive diabetic managementprogram, and
b) Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities.
4) For venous insufficiency ulcers:
a) Compression bandages and/or garments have been consistently applied, and
b) Leg elevation and ambulation have been encouraged.

B) Ulcers and Wounds Encountered in an Inpatient Setting:

1) An ulcer or wound (described under **A** above) is encountered in the inpatient setting and, after wound treatments described under **A-1 through A-4** have been tried or considered and ruled out, NPWT is initiated because it is considered in the judgment of the treating physician, the best available treatment options.
2) The patient has complications of a surgically created wound (for example, dehiscence) or a traumatic wound (for example, pre-operative flap or graft) where there is documentation of the medical necessity for accelerated formation of granulation tissue which cannot be achieved by other available topical wound treatments (for example, other conditions of the patient that will not allow for healing times achievable with other topical wound treatments).

In either situation **B-1** or **B-2**, NPWT will be covered when treatment continuation is ordered beyond discharge to the home setting.

If criterion **A** or **B** above is not met, the NPWT pump and supplies will be denied as not medically necessary.

NPWT pumps (K0538) must be capable of accommodating more than one wound dressing set for multiple wounds on a patient. Therefore, more than one K0538 billed per patient for the same time period will be denied as not medically necessary.

Other Exclusions from Coverage:

An NPWT pump and supplies will be denied at any time as not medically necessary if one or more of the following are present:

· the presence in the wound of necrotic tissue with eschar, if debridement is not attempted;
· untreated osteomyelitis within the vicinity of the wound;
· cancer present in the wound;
· the presence of a fistula to an organ or body cavity within the vicinity of the wound.

NPWT pumps and their supplies, which have not been specifically designated as being qualified for use of HCPCS codes K0538 – K0540 for billing to the DMERC via written instructions from the SADMERC, will be denied as not medically necessary.

Continued Coverage:

C) For wounds and ulcers described under **A** or **B** above, once placed on an NPWT pump and supplies, in order for coverage to continue a licensed medical professional must do the following:
1) On a regular basis,
a) directly assess the wound(s) being treated with the NPWT pump, and
b) supervise or directly perform the NPWT dressing changes, and
2) On at least a monthly basis, document changes in the ulcer's dimensions and characteristics.

If criteria **C-1** and **C-2** are not fulfilled, continued coverage of the NPWT pump and supplies will be denied as not medically necessary.

When Coverage Ends:

D) For wounds and ulcers described under **A** or **B** above, an NPWT pump and supplies will be denied as not medically necessary with any of the following, whichever occurs earliest:
1) Criteria **C1-C2** cease to occur,
2) In the judgment of the treating physician, adequate wound healing has occurred to the degree that NPWT may be discontinued,
3) Any measurable degree of wound healing has failed to occur over the prior month. There must be documented in the patient's medical records quantitative measurements of wound characteristics including wound length and width (surface area), or depth, serially observed and documented, over a specified time interval. The recorded wound measurements must be consistently and regularly updated and must have demonstrated progressive wound healing from month to month,
4) 4 months (including the time NPWT was applied in an inpatient setting prior to discharge to the home) have elapsed using an NPWT pump in the treatment of any wound. Coverage beyond 4 months will be given individual consideration based upon required additional documentation,

5) Once equipment or supplies are no longer being used for the patient, whether or not by the physician's order.

Supplies:

· Coverage is provided up to a maximum of 15 dressing kits (K0539) per wound per month unless there is documentation that the wound size requires more than one dressing kit for each dressing change.
· Coverage is provided up to a maximum of 10 canister sets (K0540) per month unless there is documentation evidencing a large volume of drainage (greater than 90 ml of exudate per day). For high volume exudative wounds, a stationary pump with the largest capacity canister must be used. Excess utilization of canisters related to equipment failure (as opposed to excessive volume drainage) will be denied as not medically necessary.

Amounts greater than 15 dressing kits (K0539) per wound per month or 10 canister sets (K0540) per month in the absence of documentation clearly explaining the medical necessity of the excess quantities will be denied as not medically necessary.

CODING GUIDELINES:

Suppliers should refer to the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) web site or contact the SADMERC for guidance on the correct coding for these devices.

DOCUMENTATION:

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. § 1395l(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

A written order for the negative pressure wound therapy pump and supplies must be signed and dated by the treating physician and obtained by the supplier prior to delivery of the item. The order must be kept on file by the supplier. The order must include the type of supplies ordered and the approxi-mate quantity to be used per unit of time.

Documentation of the history, previous treatment regimens (if applicable), and current wound management for which an NPWT pump is being billed must be present in the patient's medical record and be available for review if requested by the DMERC. This documentation must include such elements as length of sessions of use, dressing types and frequency of change, and changes in wound conditions, including precise measurements, quantity of exudates, presence of granulation and necrotic tissue and concurrent

measures being addressed relevant to wound therapy (debridement, nutritional concerns, support surfaces in use, positioning, incontinence control, etc.).

Documentation of wound evaluation and treatment, recorded in the patient's medical record, must indicate regular evaluation and treatment of the patient's wounds, as detailed in the Coverage and Payment Section. Documentation of quantitative measurements of wound characteristics including wound length and width (surface area), and depth, and amount of wound exudate (drainage), indicating progress of healing must be entered at least monthly. The supplier of the NPWT equipment and supplies must obtain from the treating clinician, an assessment of wound healing progress, based upon the wound measurement as documented in the patient's medical record, in order to determine whether the equipment and supplies continue to qualify for Medicare coverage. (The supplier need not view the medical records in order to bill for continued use of NPWT. Whether the supplier ascertains that wound healing is occurring from month to month via verbal or written communication is left to the discretion of the supplier. However, the patient's medical records may be requested by the DMERC in order to corroborate that wound healing is/was occurring as represented on the supplier's claims for reimbursement.)

If detailed documentation in the patient's medical record is insufficient, the DMERC will be unable to establish the medical necessity of the NPWT pump and supplies, and these items will be denied as not medically necessary.

When billing for NPWT, an ICD-9-CM diagnosis code (specific to the 5th digit), describing the wound being treated by NPWT, must be included on each order and on each claim for the equipment and related supplies.

If all of the conditions are met under criteria **A1-A4, B1-B2** and **C1-C2** in the Coverage and Payment Rules section, a KX modifier is to be added to the HCPCS codes on each month's claims for initial and continued use of NPWT equipment and supplies.

The KX modifier **must not be used** if all of the policy's coverage criteria for initial and continued use have not been met.

The KX modifier **must not be used** if any of the conditions (listed in the Coverage and Payment Rules section under, "Other Exclusions from Coverage" are present.

The KX modifier **must not be used** if any of the situations **D1-D5** (listed in the Coverage and Payment Rules section under, "When Coverage Ends") are present.

A KX modifier **must not be used** with an NPWT pump and supplies for wounds (described under **A** or **B** in the Coverage and Payment Rules Section) in the 5th and successive months, but additional documentation

may be submitted for individual consideration. The claim must include a statement from the treating physician describing the initial condition of the wound including measurements, efforts to address all aspects of wound care (listed in **A-1** through **A-4**). Each subsequent monthly claim should also include updated wound measurements and what changes in wound therapy are being applied to effect wound healing.

When billing for quantities of supplies greater than those described in the policy as the usual maximum amounts, each claim must include documentation supporting the medical necessity for the higher utilization. This information must be attached to a hard copy claim or entered in the HA0 record of an electronic claim.

Refer to the Supplier Manual for more information on orders, medical records, and supplier documentation.

EFFECTIVE DATE: For claims with dates of service on or after July 1, 2002.

This is a revision of previously published policy.

<<<BACK

MEDICAL POLICY

SUBJECT: Negative Pressure Wound Therapy Pumps

HCPCS CODES:

The appearance of a code in this section does not necessarily indicate coverage.

EQUIPMENT

K0538 Negative pressure wound therapy electrical pump, stationary or portable

SUPPLIES:

K0539 Dressing set for negative pressure wound therapy electrical pump, stationary or portable, each

K0540 Canister set for negative pressure wound therapy electrical pump, stationary or portable, each

HCPCS MODIFIER:

KX: Specific required documentation on file.

BENEFIT CATEGORY: Durable Medical Equipment

DEFINITIONS

Negative pressure wound therapy (NPWT) is the controlled application of subatmospheric pressure to a wound using an electrical pump (described in the definition of HCPCS code K0538) to intermittently or continuously convey subatmospheric pressure through connecting tubing to a specialized wound dressing (described in the definition of HCPCS code K0539) which includes a resilient, open-cell foam surface dressing, sealed with an occlusive dressing that is meant to contain the subatmospheric pressure at the wound site and thereby promote wound healing. Drainage from the wound is collected in a canister (described in the definition of HCPCS code K0540).

HCPCS code **K0538** describes a stationary or portable NPWT electrical pump which provides controlled subatmospheric pressure that is designed for use with NPWT dressings, (K0539) to promote wound healing. Such an NPWT pump is capable of being selectively switched between continuous and intermittent modes of operation and is controllable to adjust the degree of subatmospheric pressure conveyed to the wound in a range from 25 to $\geq$ 200 mm Hg subatmospheric pressure. The pump is capable of sounding an audible alarm when desired pressures are not being achieved (that is, where there is a leak in the dressing seal) and when its wound drainage canister (K0540) is full. The pump is designed to fill the canister to full capacity.

HCPCS code **K0539** describes a dressing set which is used in conjunction with a stationary or portable NPWT pump (K0538), and contains all necessary components, including but not limited to a resilient, open-cell foam surface dressing, drainage tubing, and an occlusive dressing which creates a seal around the wound site for maintaining subatmospheric pressure at the wound.

HCPCS code **K0540** describes a canister set which is used in conjunction with a stationary or portable NPWT pump (K0538) and contains all necessary components, including but not limited to a container, to collect wound exudate. Canisters may be various sizes to accommodate stationary or portable NPWT pumps.

A licensed health care professional, for the purposes of this policy, may be a physician, physician's assistant (PA), registered nurse (RN), licensed practical nurse (LPN), or physical therapist (PT). The practitioner should be licensed to assess wounds and/or administer wound care within the state where the beneficiary is receiving NPWT.

Lack of improvement of a wound, as used within this policy, is defined as a lack of progress in quantitative measurements of wound characteristics including wound length and width (surface area), or depth measured serially and documented, over a specified time interval. Wound healing is defined as improvement occurring in either surface area or depth of the wound.

The staging of pressure ulcers used in this policy is as follows:

Stage I	Observable pressure related alteration of intact skin whose indicators as compared to the adjacent or opposite area on the body may include changes in one of more of the following: skin temperature (warmth or coolness), tissue consistency (firm or boggy feel) and/or sensation (pain, itching). The ulcer appears as a defined area of persistent redness in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue, or purple hues.
Stage II	Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater.
Stage III	Full thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.
Stage IV	Full thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g., tendon, joint capsule). Undermining and sinus tracts also may be associated with Stage IV pressure ulcers.

COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must: 1) be eligible for a defined Medicare Benefit Category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following coverage and payment rules.

Equipment:

Initial Coverage:

An NPWT pump and supplies are covered when either criterion A or B is met:

A) Ulcers and Wounds in the Home Setting:

The patient has a chronic Stage III or IV pressure ulcer, neuropathic (for example, diabetic) ulcer, venous or arterial insufficiency ulcer, or a chronic (being present for at least 30 days) ulcer of mixed etiology. A complete wound therapy program described by criterion 1 and criteria 2, 3, or 4, as applicable depending on the type of wound, should have been tried or considered and ruled out prior to application of NPWT.

1) For all ulcers or wounds, the following components of a wound therapy program must include a minimum of all of the following general measures, which should be addressed, applied, or considered and ruled out prior to application of NPWT:
   a) Documentation in the patient's medical record of evaluation, care, and wound measurements by a licensed medical professional, and
   b) Application of dressings to maintain a moist wound environment, and
   c) Debridement of necrotic tissue if present, and
   d) Evaluation of and provision for adequate nutritional status.
2) For Stage III or IV pressure ulcers:
   a) The patient has been appropriately turned and positioned, and
   b) The patient has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis (see DMERC medical policy on support surfaces), (a group 2 or 3 support surface is not required if the ulcer is not on the trunk or pelvis) and
   c) The patient's moisture and incontinence have been appropriately changed.
3) For neuropathic (for example, diabetic) ulcers:
   a) The patient has been on a comprehensive diabetic managementprogram, and
   b) Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities.
4) For venous insufficiency ulcers:
   a) Compression bandages and/or garments have been consistently applied, and
   b) Leg elevation and ambulation have been encouraged.

B) Ulcers and Wounds Encountered in an Inpatient Setting:

1) An ulcer or wound (described under A above) is encountered in the inpatient setting and, after wound treatments described under **A-1 through A-4** have been tried or considered and ruled out, NPWT is initiated because it is considered in the judgment of the treating physician, the best available treatment options.
2) The patient has complications of a surgically created wound (for example, dehiscence) or a traumatic wound (for example, pre-operative flap or graft) where there is documentation of the medical necessity for accelerated formation of granulation tissue which cannot be achieved by other available topical wound treatments (for example, other conditions of the patient that will not allow for healing times achievable with other topical wound treatments).

   In either situation B-1 or B-2, NPWT will be covered when treatment continuation is ordered beyond discharge to the home setting.

If criterion A or B above is not met, the NPWT pump and supplies will be denied as not medically necessary.

NPWT pumps (K0538) must be capable of accommodating more than one wound dressing set for multiple wounds on a patient. Therefore, more than one K0538 billed per patient for the same time period will be denied as not medically necessary.

Other Exclusions from Coverage:

An NPWT pump and supplies will be denied at any time as not medically necessary if one or more of the following are present:

- the presence in the wound of necrotic tissue with eschar, if debridement is not attempted;
- untreated osteomyelitis within the vicinity of the wound;
- cancer present in the wound;
- the presence of a fistula to an organ or body cavity within the vicinity of the wound.

NPWT pumps and their supplies, which have not been specifically designated as being qualified for use of HCPCS codes K0538 – K0540 for billing to the DMERC via written instructions from the SADMERC, will be denied as not medically necessary.

Continued Coverage:

C) For wounds and ulcers described under A or B above, once placed on an NPWT pump and supplies, in order for coverage to continue a licensed medical professional must do the following:
   1) On a regular basis,
      a) directly assess the wound(s) being treated with the NPWT pump, and
      b) supervise or directly perform the NPWT dressing changes, and
   2) On at least a monthly basis, document changes in the ulcer's dimensions and characteristics.

If criteria C-1 and C-2 are not fulfilled, continued coverage of the NPWT pump and supplies will be denied as not medically necessary.

When Coverage Ends:

D) For wounds and ulcers described under A or B above, an NPWT pump and supplies will be denied as not medically necessary with any of the following, whichever occurs earliest:
   1) Criteria C1-C2 cease to occur,
   2) In the judgment of the treating physician, adequate wound healing has occurred to the degree that NPWT may be discontinued,
   3) Any measurable degree of wound healing has failed to occur over the prior month. There must be documented in the patient's medical records quantitative measurements of wound characteristics including wound length and width (surface area), or depth, serially observed and documented, over a specified time interval. The recorded wound measurements must be consistently and regularly updated and must have demonstrated progressive wound healing from month to month,
   4) 4 months (including the time NPWT was applied in an inpatient setting prior to discharge to the home) have elapsed using an NPWT pump in the treatment of any wound. Coverage beyond 4 months will be given individual consideration based upon required additional documentation,
   5) Once equipment or supplies are no longer being used for the patient, whether or not by the physician's order.

Supplies:

- Coverage is provided up to a maximum of 15 dressing kits (K0539) per wound per month unless there is documentation that the wound size requires more than one dressing kit for each dressing change.
- Coverage is provided up to a maximum of 10 canister sets (K0540) per month unless there is documentation evidencing a large volume of drainage (greater than 90 ml of exudate per day). For high volume exudative wounds, a stationary pump with the largest capacity canister must be used. Excess utilization of canisters related to equipment failure (as opposed to excessive volume drainage) will be denied as not medically necessary.

Amounts greater than 15 dressing kits (K0539) per wound per month or 10 canister sets (K0540) per month in the absence of documentation clearly explaining the medical necessity of the excess quantities will be denied as not medically necessary.

CODING GUIDELINES:

Suppliers should refer to the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) web site or contact the SADMERC for guidance on the correct coding for these devices.

DOCUMENTATION:

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. § 1395l(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

A written order for the negative pressure wound therapy pump and supplies must be signed and dated by the treating physician and obtained by the supplier prior to delivery of the item. The order must be kept on file by the supplier. The order must include the type of supplies ordered and the approximate quantity to be used per unit of time.

Documentation of the history, previous treatment regimens (if applicable), and current wound management for which an NPWT pump is being billed must be present in the patient's medical record and be available for review if requested by the DMERC. This documentation must include such elements as length of sessions of use, dressing types and frequency of change, and changes in wound conditions, including precise measurements, quantity of exudates, presence of granulation and necrotic tissue and concurrent measures being addressed relevant to wound therapy (debridement, nutritional concerns, support surfaces in use, positioning, incontinence control, etc.).

Documentation of wound evaluation and treatment, recorded in the patient's medical record, must indicate regular evaluation and treatment of the patient's wounds, as detailed in the Coverage and Payment Section. Documentation of quantitative measurements of wound characteristics including wound length and width (surface area), and depth, and amount of wound exudate (drainage), indicating progress of healing must be entered at least monthly. The supplier of the NPWT equipment and supplies must obtain from the treating clinician, an assessment of wound healing progress, based upon the wound measurement as documented in the patient's medical record, in order to determine whether the equipment and supplies continue to qualify for Medicare coverage. (The supplier need not view the medical records in order to bill for continued use of NPWT. Whether the supplier ascertains that wound healing is occurring from month to month via verbal or written communication is left to the discretion of the supplier. However, the patient's medical records may be requested by the DMERC in order to corroborate that wound healing is/was occurring as represented on the supplier's claims for reimbursement.)

If detailed documentation in the patient's medical record is insufficient, the DMERC will be unable to establish the medical necessity of the NPWT pump and supplies, and these items will be denied as not medically necessary.

When billing for NPWT, an ICD-9-CM diagnosis code (specific to the 5th digit), describing the wound being treated by NPWT, must be included on each order and on each claim for the equipment and related supplies.

If all of the conditions are met under criteria **A1-A4**, **B1-B2** and **C1-C2** in the Coverage and Payment Rules section, a **KX** modifier is to be added to the HCPCS codes on each month's claims for initial and continued use of NPWT equipment and supplies.

The KX modifier **must not be used** if all of the policy's coverage criteria for initial and-continued use have not been met.

The KX modifier **must not be used** if any of the conditions (listed in the Coverage and Payment Rules section under, "Other Exclusions from Coverage" are present.

The KX modifier **must not be used** if any of the situations D1-D5 (listed in the Coverage and Payment Rules section under, "When Coverage Ends") are present.

A KX modifier **must not be used** with an NPWT pump and supplies for wounds (described under A or B in the Coverage and Payment Rules Section) in the 5th and successive months, but additional documentation may be submitted for individual consideration. The claim must include a statement from the treating physician describing the initial condition of the wound including measurements, efforts to address all aspects of wound care (listed in A-1 through A-4). Each subsequent monthly claim should also include updated wound measurements and what changes in wound therapy are being applied to effect wound healing.

When billing for quantities of supplies greater than those described in the policy as the usual maximum amounts, each claim must include documentation supporting the medical necessity for the higher utilization. This information must be attached to a hard copy claim or entered in the HA0 record of an electronic claim.

Refer to the Supplier Manual for more information on orders, medical records, and supplier documentation.

EFFECTIVE DATE: For claims with dates of service on or after July 1, 2002.

This is a revision of previously published policy.

General Information
Supplier Enrollment
Ombudsman Contacts
FAQs
Coverage
Certificates of Medical Necessity
Physician Information Sheets
SADMERC
Advisories
Manuals
Medical Policies
Fee Schedules
Forms
Appeals
Benefit Integrity
Learning & Education
Related Sites
DMERC Home
Providers Home

Manuals

<<BACK

Chapter 61 - Surgical Dressings

View Attachments

Chapter 61 contains the medical policy for surgical dressings. Click on View Attachments to download the entire chapter for viewing and printing in PDF format.

MEDICAL POLICY

SUBJECT: Surgical Dressings

HCPCS CODES

The appearance of a code in this section does not necessarily indicate coverage.

A4460	Elastic bandage, per roll (e.g., compression bandage)
A4462	Abdominal dressing holder/binder, each
A4649	Surgical supply, miscellaneous
A6010	Collagen based wound filler, dry form, per gram of collagen
A6021	Collagen dressing, pad size 16 sq. in. or less, each
A6022	Collagen dressing, pad size more than 16 sq. in. but less than or equal to 48 sq. in., each
A6023	Collagen dressing, pad size more than 48 sq. in., each
A6024	Collagen dressing wound filler, per 6 inches
A6154	Wound pouch, each
A6196	Alginate or other fiber gelling dressing, wound cover, pad size 16 sq. in. or less, each dressing
A6197	Alginate or other fiber gelling dressing, wound cover, pad size more than 16 sq. in. but less than or equal to 48 sq. in., each dressing
A6198	Alginate or other fiber gelling dressing, wound cover, pad size

	more than 48 sq. in., each dressing
A6199	Alginate or other fiber gelling dressing, wound filler, per 6 inches
A6200	Composite dressing, pad size 16 sq. in. or less, without adhesive border, each dressing
A6201	Composite dressing, pad size more than 16 sq. in. but less than or equal to 48 sq. in., without adhesive border, each dressing
A6202	Composite dressing, pad size more than 48 sq. in., without adhesive border, each dressing
A6203	Composite dressing, pad size 16 sq. in. or less, with any size adhesive border, each dressing
A6204	Composite dressing, pad size more than 16 sq. in. but less than or equal to 48 sq. in., with any size adhesive border, each dressing
A6205	Composite dressing, pad size more than 48 sq. in., with any size adhesive border, each dressing
A6206	Contact layer, 16 sq. in. or less, each dressing
A6207	Contact layer, more than 16 sq. in. but less than or equal to 48 sq. in., each dressing
A6208	Contact layer, more than 48 sq. in., each dressing
A6209	Foam dressing, wound cover, pad size 16 sq. in. or less, without adhesive border, each dressing
A6210	Foam dressing, wound cover, pad size more than 16 sq. in. but less than or equal to 48 sq. in., without adhesive border, each dressing
A6211	Foam dressing, wound cover, pad size more than 48 sq. in., without adhesive border, each dressing
A6212	Foam dressing, wound cover, pad size 16 sq. in. or less, with any size adhesive border, each dressing
A6213	Foam dressing, wound cover, pad size more than 16 sq. in. but less than or equal to 48 sq. in., with any size adhesive border, each dressing
A6214	Foam dressing, wound cover, pad size more than 48 sq. in., with any size adhesive border, each dressing
A6215	Foam dressing, wound filler, per gram
A6216	Gauze, non-impregnated, non-sterile, pad size 16 sq. in. or less, without adhesive border, each dressing
A6217	Gauze, non-impregnated, non-sterile, pad size more than 16 sq. in. but less than or equal to 48 sq. in., without adhesive border, each dressing
A6218	Gauze, non-impregnated, non-sterile, pad size more than 48 sq. in., without adhesive border, each dressing
A6219	Gauze, non-impregnated, pad size 16 sq. in. or less, with any size adhesive border, each dressing

A6221	Gauze, non-impregnated, pad size more than 48 sq. in., with any size adhesive border, each dressing
A6222	Gauze, impregnated, other than water or normal saline, or hydrogel, pad size 16 sq. in. or less, without adhesive border, each dressing
A6223	Gauze, impregnated, other than water or normal saline, or hydrogel, pad size more than 16 sq. in. but less than or equal to 48 sq. in., without adhesive border, each dressing
A6224	Gauze, impregnated, other than water or normal saline, or hydrogel, pad size more than 48 sq. in., without adhesive border, each dressing
A6228	Gauze, impregnated, water or normal saline, pad size 16 sq. in. or less, without adhesive border, each dressing
A6229	Gauze, impregnated, water or normal saline, pad size more than 16 sq. in. but less than or equal to 48 sq. in., without adhesive border, each dressing
A6230	Gauze, impregnated, water or normal saline, pad size more than 48 sq. in., without adhesive border, each dressing
A6231	Gauze, impregnated, hydrogel, for direct wound contact, pad size 16 sq. in. or less, each dressing
A6232	Gauze, impregnated, hydrogel, for direct wound contact, pad size greater than 16 sq. in. but less than or equal to 48 sq. in., each dressing
A6233	Gauze, impregnated, hydrogel, for direct wound contact, pad size more than 48 sq. in., each dressing
A6234	Hydrocolloid dressing, wound cover, pad size 16 sq. in. or less, without adhesive border, each dressing
A6235	Hydrocolloid dressing, wound cover, pad size more than 16 sq. in. but less than or equal to 48 sq. in., without adhesive border, each dressing
A6236	Hydrocolloid dressing, wound cover, pad size more than 48 sq. in., without adhesive border, each dressing
A6237	Hydrocolloid dressing, wound cover, pad size 16 sq. in. or less, with any size adhesive border, each dressing
A6238	Hydrocolloid dressing, wound cover, pad size more than 16 sq. in. but less than or equal to 48 sq. in., with any size adhesive border, each dressing
A6239	Hydrocolloid dressing, wound cover, pad size more than 48 sq. in., with any size adhesive border, each dressing
A6240	Hydrocolloid dressing, wound filler, paste, per fluid ounce
A6241	Hydrocolloid dressing, wound filler, dry form, per gram
A6242	Hydrogel dressing, wound cover, pad size 16 sq. in. or less, without adhesive border, each dressing

A6244	Hydrogel dressing, wound cover, pad size more than 48 sq. in., without adhesive border, each dressing
A6245	Hydrogel dressing, wound cover, pad size 16 sq. in. or less, with any size adhesive border, each dressing
A6246	Hydrogel dressing, wound cover, pad size more than 16 sq. in. but less than or equal to 48 sq. in., with any size adhesive border, each dressing
A6247	Hydrogel dressing, wound cover, pad size more than 48 sq. in., with any size adhesive border, each dressing
A6248	Hydrogel dressing, wound filler, gel, per fluid ounce
A6250	Skin sealants, protectants, moisturizers, ointments, any type, any size
A6251	Specialty absorptive dressing, wound cover, pad size 16 sq. in. or less, without adhesive border, each dressing
A6252	Specialty absorptive dressing, wound cover, pad size more than 16 sq. in. but less than or equal to 48 sq. in., without adhesive border, each dressing
A6253	Specialty absorptive dressing, wound cover, pad size more than 48 sq. in., without adhesive border, each dressing
A6254	Specialty absorptive dressing, wound cover, pad size 16 sq. in. or less, with any size adhesive border, each dressing
A6255	Specialty absorptive dressing, wound cover, pad size more than 16 sq. in. but less than or equal to 48 sq. in., with any size adhesive border, each dressing
A6256	Specialty absorptive dressing, wound cover, pad size more than 48 sq. in., with any size adhesive border, each dressing
A6257	Transparent film, 16 sq. in. or less, each dressing
A6258	Transparent film, more than 16 sq. in. but less than or equal to 48 sq. in., each dressing
A6259	Transparent film, more than 48 sq. in., each dressing
A6260	Wound cleansers, any type, any size
A6261	Wound filler, gel/paste, per fluid ounce, not elsewhere classified
A6262	Wound filler, dry form, per gram, not elsewhere classified
A6263	Gauze, elastic, non-sterile, all types, per linear yard
A6264	Gauze, non-elastic, non-sterile, per linear yard
A6266	Gauze, impregnated, other than water or normal saline, any width, per linear yard
A6402	Gauze, non-impregnated, sterile, pad size 16 sq. in. or less, without adhesive border, each dressing
A6403	Gauze, non-impregnated, sterile, pad size more than 16 sq. in. but less than or equal to 48 sq. in., without adhesive border, each dressing

A6404	Gauze, non-impregnated, sterile, pad size more than 48 sq. in., without adhesive border, each dressing
A6405	Gauze, elastic, sterile, all types, per linear yard
A6406	Gauze, non-elastic, sterile, all types, per linear yard
A9270	Non-covered item or service
K0572	Tape, non-waterproof, per 18 square inches
K0573	Tape, waterproof, per 18 square inches

HCPCS MODIFIERS

X1	Dressing used as a primary or secondary dressing on one surgical or debrided wound
X2	Dressing used as a primary or secondary dressing on two surgical or debrided wounds
X3	Dressing used as a primary or secondary dressing on three surgical or debrided wounds
X4	Dressing used as a primary or secondary dressing on four surgical or debrided wounds
X5	Dressing used as a primary or secondary dressing on five surgical or debrided wounds
X6	Dressing used as a primary or secondary dressing on six surgical or debrided wounds
X7	Dressing used as a primary or secondary dressing on seven surgical or debrided wounds
X8	Dressing used as a primary or secondary dressing on eight surgical or debrided wounds
X9	Dressing used as a primary or secondary dressing on nine or more surgical or debrided wounds
GY	Item or service statutorily non-covered or does not meet the definition of any Medicare benefit

BENEFIT CATEGORY: Surgical Dressings

REFERENCE: CIM 45-12

DEFINITIONS
Wound fillers are dressing materials which are placed into open wounds to eliminate dead space, absorb exudate, or maintain a moist wound surface.

Wound covers are flat dressing pads. A wound cover with adhesive border is one which has an integrated cover and distinct adhesive border designed to adhere tightly to the skin.

In this policy, the term alginate includes other fiber gelling dressings.

Composite dressings are products combining physically distinct components into a single dressing that provides multiple functions. These functions must include, but are not limited to: (a) a bacterial barrier, (b) an absorptive layer other than an alginate, foam, hydrocolloid, or hydrogel, and (c) either a semi-adherent or nonadherent property over the wound site.

Contact layers are thin non-adherent sheets placed directly on an open wound bed to protect the wound tissue from direct contact with other agents or dressings applied to the wound. They are porous to allow wound fluid to pass through for absorption by an overlying dressing.

Impregnated gauze dressings are woven or non-woven materials into which substances such as iodinated agents, petrolatum, zinc compounds, crystalline sodium chloride, chlorhexadine gluconate (CHG), bismuth tribromophenate (BTP), water, aqueous saline, hydrogel, or other agents have been incorporated into the dressing material by the manufacturer.

Specialty absorptive dressings are unitized multilayer dressings which provide (a) either a semi-adherent quality or nonadherent layer, and (b) highly absorptive layers of fibers such as absorbent cellulose, cotton, or rayon. These may or may not have an adhesive border.

A wound pouch is a waterproof collection device with a drainable port that adheres to the skin around a wound.

The staging of pressure ulcers used in this policy is as follows:

Stage I	Observable pressure-related alteration of intact skin whose indicators, as compared to the adjacent or opposite area on the body, may include changes in one or more of the following: skin temperature (warmth or coolness), tissue consistency (firm or boggy feel) and/or sensation (pain, itching). The ulcer appears as a defined area of persistent redness in lightly pigmented skin, whereas in darker skin tones, the ulcer may appear with persistent red, blue, or purple hues.
Stage II	Partial thickness skin loss involving epidermis, dermis, or both. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater.
Stage III	Full thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.
Stage IV	Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone, or supporting structures (e.g., tendon, joint capsule). Undermining and sinus tracts also may be associated with Stage IV pressure ulcers.

COVERAGE AND PAYMENT RULES

For any item to be covered by Medicare, it must (1) be eligible for a defined Medicare Benefit Category, (2) be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member, and (3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this regional medical review policy, "reasonable and necessary" is defined by the following coverage and payment rules.

Surgical dressings are covered when either of the following criteria are met:

1. They are medically necessary for the treatment of a wound caused by, or treated by, a surgical procedure; or
2. They are medically necessary when debridement of a wound is medically necessary.

Surgical dressings include both primary dressings (i.e. therapeutic or protective coverings applied directly to wounds or lesions either on the skin or caused by an opening to the skin) or secondary dressings (i.e. materials that serve a therapeutic or protective function and that are needed to secure a primary dressing).

The surgical procedure or debridement must be performed by a physician or other health care professional to the extent permissible under state law. Debridement of a wound may be any type of debridement (examples given are not all-inclusive): surgical (e.g. sharp instrument or laser), mechanical (e.g., irrigation or wet-to-dry dressings), chemical (e.g., topical application of enzymes), or autolytic (e.g., application of occlusive dressings to an open wound). Dressings used for mechanical debridement, to cover chemical debriding agents, or to cover wounds to allow for autolytic debridement are covered although the agents themselves are non-covered.

Surgical dressings are covered for as long as they are medically necessary. Dressings over a percutaneous catheter or tube (e.g., intravascular, epidural, nephrostomy, etc.) are covered as long as the catheter or tube remains in place and after removal until the wound heals. (Refer to Coding Guidelines.)

Examples of situations in which dressings are non-covered under the Surgical Dressings benefit are:

a. drainage from a cutaneous fistula which has not been caused by or treated by a surgical procedure; or
b. a Stage I pressure ulcer; or
c. a first degree burn; or
d. wounds caused by trauma which do not require surgical closure or debridement - e.g. skin tear or abrasion; or
e. a venipuncture or arterial puncture site (e.g., blood sample) other than the site of an indwelling catheter or needle

Surgical dressing codes billed without modifiers X1- X9 (See Coding Guidelines) are non-covered under the Surgical Dressing Benefit. Certain dressings may be covered under other benefits (e.g., see Ostomy Supplies Policy).

If a physician applies surgical dressings as part of a professional service that is billed to Medicare, the surgical dressings are considered incident to the professional services of the health care practitioner and are not separately payable. Claims for these dressings must not be submitted to the DMERC. Claims for the professional service which includes the dressings must be submitted to the local carrier or intermediary. If dressing changes are sent home with the patient, claims for these may be submitted to the DMERC. In this situation, use the place of service corresponding to the patient's residence; Place of Service Office (POS=11) must not be used.

Surgical dressings used in conjunction with investigational wound healing therapy (e.g., platelet derived wound healing formula) may be covered if all applicable coverage criteria are met based on the number and type of surgical dressings that are appropriate to treat the wound if the investigational therapy were not being used.

When a wound cover with an adhesive border is being used, no other dressing is needed on top of it, and additional tape is usually not required. Reasons for use of additional tape must be well documented. An adhesive border is usually more binding than that obtained with separate taping and is therefore indicated for use with wounds requiring less frequent dressing changes.

Use of more than one type of wound filler or more than one type of wound cover in a single wound is rarely be medically necessary and the reasons must be well documented. An exception is an alginate wound cover or a saline, water, or hydrogel impregnated gauze dressing which might need an additional wound cover.

It may not be appropriate to use some combinations of a hydrating dressing on the same wound at the same time as an absorptive dressing (e.g., hydrogel and alginate).

Because composite dressings, foam and hydrocolloid wound covers, and transparent film, when used as secondary dressings, are meant to be changed at frequencies less than daily, appropriate clinical judgement should be used to avoid their use with primary dressings which would require more frequent dressing changes. When claims are submitted for these dressing for changes greater than once every other day, the quantity in excess of that amount will be denied as not medically necessary. While a highly exudative wound might require such a combination initially, with continued proper management the wound should progress to a point where the appropriate selection of these products should result in the less frequent dressing changes which they are designed to allow. An example of an

inappropriate combination would be the use of a specialty absorptive dressing on top of non-impregnated gauze being used as a primary dressing.

Dressing size must be based on and appropriate to the size of the wound. For wound covers, the pad size is usually about 2 inches greater than the dimensions of the wound. For example, a 5 cm x 5 cm (2 in. x 2 in.) wound requires a 4 in. x 4 in. pad size.

The following are examples of wound care items which are non-covered under the surgical dressing benefit: skin sealants or barriers (A6250), wound cleansers (A6260) or irrigating solutions, solutions used to moisten gauze (e.g., saline), silicone gel sheets, topical antiseptics, topical antibiotics, enzymatic debriding agents, gauze or other dressings used to cleanse or debride a wound but not left on the wound. Also any item listed in the latest edition of the Orange Book (e.g., an antibiotic-impregnated dressing which requires a prescription) is considered a drug and is non-covered under the Surgical Dressings benefit.

The quantity and type of dressings dispensed at any one time must take into account the current status of the wound(s), the likelihood of change, and the recent use of dressings.

Dressing needs may change frequently (e.g., weekly) in the early phases of wound treatment and/or with heavily draining wounds. Suppliers are also expected to have a mechanism for determining the quantity of dressings that the patient is actually using and to adjust their provision of dressings accordingly. No more than a one month's supply of dressings may be provided at one time, unless there is documentation to support the necessity of greater quantities in the home setting in an individual case. An even smaller quantity may be appropriate in the situations described above.

Surgical dressings must be tailored to the specific needs of an individual patient. When surgical dressings are provided in kits, only those components of the kit that meet the definition of a surgical dressing, are ordered by the physician, and are medically necessary are covered.

The following are some specific coverage guidelines for individual products when the products themselves are necessary in the individual patient. The medical necessity for more frequent change of dressing must be documented in the patient's medical record and submitted with the claim to the DMERC (see Documentation section).

Alginate dressing (A6196-A6199)
Alginate dressing covers are covered for moderately to highly exudative full thickness wounds (e.g., stage III or IV ulcers); and alginate fillers for moderately to highly exudative full thickness wound cavities (e.g., stage III or IV ulcers). They are not medically necessary on dry wounds or wounds covered with eschar. Usual dressing change is up to once per day. One wound cover sheet of the approximate size of the wound or up to 2 units of wound filler (1 unit = 6 inches of alginate rope) is usually used at each

dressing change. It is usually inappropriate to use alginates in combination with hydrogels.

Composite dressing (A6200-A6205)
Usual composite dressing change is up to 3 times per week, one wound cover per dressing change.

Contact layer (A6206-A6208)
Contact layer dressings are used to line the entire wound; they are not intended to be changed with each dressing change. Usual dressing change is up to once per week.

Foam dressing (A6209-A6215)
Foam dressings are covered when used on full thickness wounds (e.g., stage III or IV ulcers) with moderate to heavy exudate. Usual dressing change for a foam wound cover used as a primary dressing is up to 3 times per week. When a foam wound cover is used as a secondary dressing for wounds with very heavy exudate, dressing change may be up to 3 times per week. Usual dressing change for foam wound fillers is up to once per day.

Gauze, non-impregnated (A6216-A6221, A6402-A6404)
Usual non-impregnated gauze dressing change is up to 3 times per day for a dressing without a border and once per day for a dressing with a border. It is usually not necessary to stack more than 2 gauze pads on top of each other in any one area.

Gauze, impregnated, with other than water, normal saline, or hydrogel (A6222-A6224, A6266)
Usual dressing change for gauze dressings impregnated with other than water, normal saline, or hydrogel is up to once per day.

Gauze, impregnated, water or normal saline (A6228-A6230)
There is no medical necessity for these dressings compared to non-impregnated gauze which is moistened with bulk saline or sterile water. When these dressings are billed, payment will be based on the least costly medically appropriate alternative, sterile non-impregnated gauze. Bulk saline or sterile water is non-covered under the Surgical Dressings benefit.

Hydrocolloid dressing (A6234-A6241)
Hydrocolloid dressings are covered for use on wounds with light to moderate exudate. Usual dressing change for hydrocolloid wound covers or hydrocolloid wound fillers is up to 3 times per week.

Hydrogel dressing (A6231-A6233, A6242-A6248)
Hydrogel dressings are covered when used on full thickness wounds with minimal or no exudate (e.g., stage III or IV ulcers). Hydrogel dressings are not usually medically necessary for stage II ulcers . Documentation must substantiate the medical necessity for use of hydrogel dressings for stage II ulcers (e.g., location of ulcer is sacro-coccygeal area). Usual dressing change for hydrogel wound covers without adhesive border or hydrogel

wound fillers is up to once per day. Usual dressing change for hydrogel wound covers with adhesive border is up to 3 times per week.

The quantity of hydrogel filler used for each wound should not exceed the amount needed to line the surface of the wound. Additional amounts used to fill a cavity are not medically necessary. Documentation must substantiate the medical necessity for code A6248 billed in excess of 3 units (fluid ounces) per wound in 30 days.

Use of more than one type of hydrogel dressing (filler, cover, or impregnated gauze) on the same wound at the same time is not medically necessary.

Specialty absorptive dressing (A6251-A6256)
Specialty absorptive dressings are covered when used for moderately or highly exudative wounds (e.g., stage III or IV ulcers). Usual specialty absorptive dressing change is up to once per day for a dressing without an adhesive border and up to every other day for a dressing with a border.

Transparent film (A6257-A6259)
Transparent film dressings are covered when used on open partial thickness wounds with minimal exudate or closed wounds. Usual dressing change is up to 3 times per week.

Wound filler, not elsewhere classified (A6261-A6262)
Usual dressing change is up to once per day.

Wound pouch (A6154)
Usual dressing change is up to 3 times per week.

Tape (K0572, K0573)
Tape is covered when needed to hold on a wound cover, elastic roll gauze or non-elastic roll gauze. Additional tape is usually not required when a wound cover with an adhesive border is used. The medical necessity for tape in these situations must be documented. Tape change is determined by the frequency of change of the wound cover. Quantities of tape submitted must reasonably reflect the size of the wound cover being secured. Usual use for wound covers measuring 16 square inches or less is up to 2 units per dressing change; for wound covers measuring 16 to 48 square inches, up to 3 units per dressing change; for wound covers measuring greater than 48 square inches, up to 4 units per dressing change.

Elastic bandage (A4460), Elastic gauze (A6263, A6405), Non-elastic gauze (A6264, A6406)
Elastic bandages and elastic and non-elastic gauze are covered when they are used to hold wound cover dressings in place. These items are also covered when they are part of a multi-layer compression bandage system used in the treatment of a venous stasis ulcer. Elastic bandages and elastic and non-elastic gauze are non-covered when used for strains, sprains, edema, or situations other than as a dressing for a wound.

Most elastic bandages are reusable. Usual frequency of replacement would be no more than one per week unless they are part of a multi-layer compression bandage system.

Elastic and non-elastic gauze dressing change is determined by the frequency of change of the selected underlying dressing.

Compression Burn Garments
Compression burn garments are covered under the Surgical Dressings benefit when they are used to reduce hypertrophic scarring and joint contractures following a burn injury.

CODING GUIDELINES

When dressings are covered under other benefits -- e.g. durable medical equipment (infusion pumps) or prosthetic devices (parenteral and enteral nutrition, tracheostomy) -- and are included in supply allowance codes -- e.g. A4221 with a covered infusion pump, B4224 with parenteral nutrition, B4034-B4036 with enteral nutrition, A4625 or A4629 with a tracheostomy -- they may not be separately billed using the surgical dressing codes. Dressings over infusion access entry sites not used in conjunction with covered use of infusion pumps, or over catheter/tube entry sites into a body cavity (other than tracheostomy) are billed separately using the appropriate surgical dressing code.

Wound fillers come in hydrated forms (e.g. pastes, gels), dry forms (e.g. powder, granules, beads), or other forms such as rope, spiral, pillows, etc. For certain materials, unique codes have been established -- i.e., collagen wound filler (A6010, A6024), alginate wound filler (A6199), foam wound filler (A6215), hydrocolloid wound filler (A6240, A6241), and hydrogel wound filler (A6248). Wound fillers not falling into any of these categories would be coded as A6261 or A6262.

The units of service for wound fillers are 1 gram, 1 fluid ounce, or 6 inch length depending on the product. If the individual product is packaged as a fraction of a unit (e.g., 1/2 fluid ounce), determine the units billed by multiplying the number dispensed times the individual product size and rounding to the nearest whole number. For example, if eleven (11) 1/2 oz. tubes of a wound filler are dispensed, bill 6 units (11 x 1/2 = 5.5; round to 6).

For some wound fillers, the units on the package do not correspond to the units of the new code. For example, some pastes or gels are labelled as grams (instead of fluid ounces), some wound fillers are labelled as cc. or ml. (instead of fluid ounces or grams), some are described by linear dimensions (instead of grams). In these situations, the supplier must contact the manufacturer to determine the appropriate conversion factor or unit of service which corresponds to the new code.

Some wound covers are available both without and with an adhesive border. For wound covers with an adhesive border, the code to be used is determined by the pad size, not by the outside adhesive border dimensions. For example, a hydrocolloid dressing with outside dimensions of 6 in. x 6 in. which has a 4 in. x 4 in. pad surrounded by a 1 in. border on each side is coded as A6237, "... pad size 16 sq. inch or less ..."

Products containing multiple materials are categorized according to the clinically predominant component (e.g., alginate, collagen, foam, gauze, hydrocolloid, hydrogel). Other multi-component wound dressings not containing these specified components may be classified as composite or specialty absorptive dressings if the definition of these categories has been met. Multi-component products may not be unbundled and billed as the separate components of the dressing.

Gauze or gauze-like products are typically manufactured as a single piece of material folded into a several ply gauze pad. Coding must be based on the functional size of the pad as it is commonly used in clinical practice.

For all dressings, if a single dressing is divided into multiple portion/pieces, the code and quantity billed must represent the originally manufactured size and quantity.

Impregnated dressings that are listed in the FDA Orange Book must be billed using code A9270 and must not be billed using codes A6222-A6224, A6231-A6233, or A6266.

Code A6265 (tape, all types, per 18 square inches) is not valid for claim submission to the DMERC. Use code K0572 or K0573 instead.

Modifiers (X1-X9) have been established to indicate that a particular item is being used as a primary or secondary dressing on a surgical or debrided wound and also to indicate the number of wounds on which that dressing is being used. For example,

X1	Dressing used as a primary or secondary dressing on one surgical or debrided wound.
X2	Dressing used as a primary or secondary dressing on two surgical or debrided wounds.
X9	Dressing used as a primary or secondary dressing on nine or more surgical or debrided wounds.

The modifier number must correspond to the number of wounds on which the dressing is being used, not the total number of wounds treated. For example, if the patient has four (4) wounds but a particular dressing is only used on two (2) of them, the X2 modifier should be used with that HCPCS code.

If the dressing is not being used as a primary or secondary dressing on a

surgical or debrided wound, do not use modifiers X1-X9. When dressings are provided in non-covered situations (e.g., use of gauze in the cleansing of a wound or intact skin), a GY modifier must be added to the code and a brief description of the reason for non-coverage included -- e.g., "A6216GY -- used for wound cleansing."

When dressing codes are billed for items covered under another benefit (e.g., gauze for a continent ostomy which is covered under the prosthetic device benefit) claims must be billed according to the documentation requirements specified in the applicable policy (See Ostomy Supplies policy for details.)

When multi-layer compression bandage systems are used for the treatment of a venous stasis ulcer, each component is billed using a specific code for the component, if available -- e.g., non-sterile elastic roll gauze (A6263), non-sterile non-elastic roll gauze (A6264), elastic bandage (A4460). If there is no specific code to describe the component, use code A4649. Impregnated roll gauze dressings designed for the treatment of venous stasis ulcers are coded using A6266.

Suppliers should refer to the Surgical Dressings Product Classification List on the Statistical Analysis DME Regional Carrier (SADMERC) Web site or contact the SADMERC for guidance on the correct coding for these items.

DOCUMENTATION

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. §13951(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

An order for surgical dressings must be signed and dated by the treating physician. This order must be kept on file by the supplier.

The order must specify (a) the type of dressing (e.g. hydrocolloid wound cover, hydrogel wound filler, etc.), (b) the size of the dressing (if appropriate), (c) the number/amount to be used at one time (if more than one), (d) the frequency of dressing change, and (e) the expected duration of need.

A new order is needed if a new dressing is added or if the quantity of an existing dressing to be used is increased. A new order is not routinely needed if the quantity of dressings used is decreased. However, a new order is required at least every 3 months for each dressing being used even if the quantity used has remained the same or decreased.

Information defining the number of surgical/debrided wounds being treated with a dressing, the reason for dressing use (e.g., surgical wound, debrided wound, etc.), and whether the dressing is being used as a primary or secondary dressing or for some noncovered use (e.g. wound cleansing) must be obtained from the physician, nursing home, or home care nurse. The source of that information and date obtained should be documented in the supplier's records.

Current clinical information which supports the reasonableness and necessity of the type and quantity of surgical dressings provided must be present in the patient's medical records. Evaluation of a patient's wound(s) must be performed at least on a monthly basis unless there is documentation in the medical record which justifies why an evaluation could not be done within this timeframe and what other monitoring methods were used to evaluate the patient's need for dressings. Evaluation is expected on a more frequent basis (e.g., weekly) in patients in a nursing facility or in patients with heavily draining or infected wounds. The evaluation may be performed by a nurse, physician or other health care professional. This evaluation must include the type of each wound (e.g., surgical wound, pressure ulcer, burn, etc.), its location, its size (length x width in cm.) and depth, the amount of drainage, and any other relevant information. This information does not have to be routinely submitted with each claim. However, a brief statement documenting the medical necessity of any quantity billed which exceeds the quantity needed for the usual dressing change frequency stated in the policy must be submitted with the claim, This statement may be attached to a hard copy claim or entered in the HA0 record of an electronic claim.

When surgical dressings are billed, the appropriate modifier (X1-X9 or GY) must be added to the code when applicable. If X9 is used, information must be submitted with the claim indicating the number of wounds. If GY is used, a brief description of the reason for non-coverage (e.g., "A6216GY -- used for wound cleansing") must be included. These statements must be included with a hard copy claim or entered into the HA0 record of an electronic claim.

When codes A4649, A6261 or A6262 are used for a dressing, the appropriate modifier to indicate the number of wounds must be used and the claim must include the brand name, product number and size of the product provided. When code A4649 is used for a dressing, the claim should also include a statement describing the medical necessity for that dressing in that patient.

Refer to the Supplier Manual for more information on orders, medical records, and supplier documentation.

EFFECTIVE DATE: Claims for dates of service on or after April 1, 2002.

This is a revision of a previously published policy.

≪BACK

General Information
Supplier Enrollment
Ombudsman Contacts
FAQs
Coverage
Certificates of Medical Necessity
Physician Information Sheets
SADMERC
Advisories
Manuals
Medical Policies
Fee Schedules
Forms
Appeals
Benefit Integrity
Learning & Education
Related Sites
DMERC Home
Providers Home

Manuals

<<BACK

Chapter 62 - Tracheostomy Care Supplies

View Attachments

Chapter 62 contains the medical policy for tracheostomy care supplies. Click on View Attachments to download the entire chapter for viewing and printing in PDF format.

MEDICAL POLICY

SUBJECT: Tracheostomy Care Supplies

HCPCS CODES

The appearance of a code in this section does not necessarily indicate coverage.

A4625	Tracheostomy care kit for a new tracheostomy
A4626	Tracheostomy cleaning brush, each
A4629	Tracheostomy care kit for established tracheostomy

BENEFIT CATEGORY: Prosthetic Devices

DEFINITION
A tracheostomy care or cleaning starter kit (A4625) contains the following:

a. plastic tray
b. basin
c. pair of sterile gloves
d. tube brush
e. pipe cleaners
f. pre-cut tracheostomy dressing
g. roll of gauze
h. 4x4 sponges
i. cotton tip applicators
j. inches twill tape

A tracheostomy care kit for an established tracheostomy (A4629) contains the following:

a. tube brush
b. pipe cleaners
c. cotton tip applicators
d. twill tape
e. 4x4 sponges

COVERAGE AND PAYMENT RULES

A tracheostomy care kit is covered for a patient following an open surgical tracheostomy which has been open or is expected to remain open for at least three months.

A tracheostomy care or cleaning starter kit (A4625) is covered for the first two weeks following an open surgical tracheostomy. Beginning two weeks post-operatively, code A4625 is no longer medically necessary and, if that code is billed, payment is based on the least costly alternative, code A4629.

One tracheostomy care kit (A4625, A4629) per day is considered necessary for routine care of a tracheostomy. Claims for additional kits for non-routine tracheostomy care must be accompanied by substantiating documentation.

For information on tracheal suction catheters and related supplies, see the Suction Pump policy.

CODING GUIDELINES

A Column II code is included in the allowance for the corresponding Column I code when provided at the same time.

Column I	Column II
A4625	A4626
A4629	A4626

Tracheostomy care kits provided in the first two postoperative weeks should be coded as A4625. Tracheostomy care kits provided after the first two postoperative weeks should be coded as A4629.

DOCUMENTATION

An order for tracheostomy care supplies, which is signed and dated by the ordering physician, must be kept on file by the supplier. The physician's records must contain information which supports the medical necessity of the item ordered.

When billing for more than one tracheostomy care kit (A4625, A4629) per day, documentation must be submitted with the claim explaining the medical necessity for the greater amount.

See the Region *C DMEPOS Supplier Manual* for more information on orders, medical records and supplier documentation.

EFFECTIVE DATE: Claims with dates of service on or after November 1, 1996.

This is a revision to a previously published policy.

NOTE: Span dates (i.e., a span of time between the"from" and "to" dates of service) are required for tracheostomy care supplies, HCPCS codes A4625 and A4629.

<<<BACK

Region C DMEPOS Supplier Manual (updated through Autumn 2002)
....Change of Address Notification Form
....Contents
....Index
....Part I - General Information
.....Chapter 1 - Beneficiary Eligibility & Supplier Responsibility
.....Chapter 2 - Jurisdiction
.....Chapter 3 - National Supplier Clearinghouse
.....Chapter 4 - Statistical Analysis DMERC
.....Chapter 5 - Claims Filing
.....Chapter 6 - Documentation Requirements
.....Chapter 7 - Advance Beneficiary Notice
.....Chapter 8 - Durable Medical Equipment
.....Chapter 9 - Pricing
.....Chapter 10 - Claim Payment
.....Chapter 11 - Medicare Assignment Agreement
.....Chapter 12 - Medicare as Secondary Payer
.....Chapter 13 - Multifunctional Teams & Professional Relations
.....Chapter 14 - Appeals Process
.....Chapter 15 - Fraud & Abuse
.....Chapter 16 - Regionalization of Medical Policy
.....Chapter 17 - Internet Web Sites
....Part II - Medical Policies
.....Chapter 18 - Medical Policy
.....Chapter 19-A Intrapulmonary Percussive Ventilation System
.....Chapter 19 - Oxygen
.....Chapter 20 - Nebulizers
.....Chapter 21 - Canes and Crutches
.....Chapter 22 - Walkers
.....Chapter 23 - Commodes
.....Chapter 24 - Manual Wheelchair Base

Reporting Parenteral Nutrition Grams of Protein

Pre-mixed solutions, grams of protein or amino acid per day must be reported on the certification form. To convert volume and concentration to grams of protein, the following formula must be used:

Milliliters of Solution* ÷ 100 x *Concentration=Grams of Protein

Fractions of a gram are always rounded up to the next whole gram.

Example: Prescription is for Travasol 8.5%, 750 ml per day

750 *ml* ÷ 8.5=63.75 *Rounded to* 64 *Grams of Protein per Day*

The grams of amino acid determines which procedure code will be used to bill the TPN solution.

Reporting Units of Lipids

For proper payment of lipids, use the following formula:

***Milliliters of Lipids* x *Number of Infusions (Of Lipids) During Billing Period* ÷ 500**

NOTE: Lipids are billed by number of units. 500ml of lipids=1 unit.

Example: Prescription is for 400ml of lipids, three times/week and billed for a 31 day month.

400*ml* x 13 *Infusions* ÷ 500=10 *Units*

Special Parenteral Nutrition Solutions

Unlike the method of reporting units as days for other pre-mixed solutions, units for special solutions (codes B5000, B5100, and B5200) are reported in Item 24G of the HCFA-1500 (12/90) form as grams per day multiplied by number of days.

Example: Prescription is for Nephramine 5.4%, 250 ml per day and billed for the month of April 1996.

250 ÷ 100 x 5.4=13.5 *Rounded to* 14 x 30 *Days*=420 *Units*

Date	Place	Code	Charge	Units
04/01/92--04/30/92	12	B5000	$3,500.00	420

NOTE: Medicare will only pay for a one-month supply at a time.

NOTE: Span dates (i.e., a span of time between the "from" and "to" dates of service) are required when billing for enteral nutrition formulae, parenteral solutions and all supply kits.

Intra-peritoneal Nutrition

The DMERC Regional Medical Review Policy on Parenteral Nutrition defines parenteral nutrition as the provision of nutritional requirements intravenously. When billing nutrients, supplies or pumps that are used for intra-peritoneal nutrition (sometimes associated with peritoneal dialysis), use HCPCS code B9999 (Not Otherwise Classified for parenteral supplies). Do not use the specific B codes for parenteral nutrients based on protein content, etc., when nutrients are used in this fashion.

The calorie requirement stating "Most patients require between 20 and 35 calories/kg per day to maintain weight and strength" has been eliminated effective 4/01/02.

General Information
Supplier Enrollment
Ombudsman Contacts
FAQs
Coverage
Certificates of Medical Necessity
Physician Information Sheets
SADMERC
Advisories
Manuals
Medical Policies
Fee Schedules
Forms
Appeals
Benefit Integrity
Learning & Education
Related Sites
DMERC Home
Providers Home

Manuals

<<BACK

Chapter 63 - General Parenteral/Enteral Nutrition Therapy Information

View Attachments

Chapter 63 contains the medical policy for general parenteral/enteral nutrition therapy information. Click on View Attachments to download the entire chapter for viewing and printing in PDF format.

Change of PEN Supplier

If a beneficiary changes PEN suppliers during the course of treatment, payment made to the previous supplier or to the beneficiary can impact reimbursement to the new supplier. The following rules have been established for those suppliers who obtain new business from beneficiaries already receiving Parenteral or Enteral Nutritional therapy.

Pumps and Poles

If the pump or pole was purchased and Medicare provided purchase benefits, the equipment is owned by the beneficiary. No additional Medicare benefits will be provided for rental or purchase of items already owned by the beneficiary. In addition, if the beneficiary sells or discards the owned equipment, future rental or purchase of the same equipment is the responsibility of the beneficiary. If the patient is renting the pump or pole and a rental payment has been made for the month in which a change of suppliers occurs, another rental payment will not be made within the same month to the new supplier. The patient is expected to be allowed to continue to use the equipment for the duration of that month.

Nutrients and Supplies

Nutrients and supplies are usually provided in quantities sufficient to meet the patient's nutritional needs for a one-month period. When a change in suppliers occurs before the end of the one-month period, overlapping or duplicate services rendered by the new supplier may occur. The nutrients and supplies provided by the previous supplier are owned by the beneficiary and should be used to meet his or her nutritional requirements for the

remaining portion of the month.

Example
When a patient is transferred from one nursing facility to another, the remaining nutrients, supplies and equipment already paid for by Medicare should be transferred with the patient. The former nursing facility does not own these items or services.

Certificate of Medical Necessity (CMN) and Recertification
If a change in PEN suppliers occurs, a new initial CMN should not be submitted by the new supplier. CMNs and any recertification provided by the previous supplier are acceptable for the new supplier's claims. However, it is the responsibility of the new supplier to obtain the necessary information prior to claim submission.

Parenteral and Enteral Nutrition (PEN) Infusion Pump Rental Limitations
Effective April 1, 1990, rental payments for nutrition infusion pumps are limited to 15 months during a period of medical need. Medicare will count all rental payments made prior to April 1, 1990 toward that 15-month limit. Additional payments will not be allowed if 15 months of rental was paid prior to April 1, 1990 or, once the 15-month limit is reached. Effective October 1, 1993, PEN pumps are subject to all "capped rental" guidelines, excluding the 25% reduction payment during the 4th month of rental and thereafter. The supplier must also give the patient the option of purchase after ten months of rental. If the rental option is chosen, Medicare continues making rental payments for an additional five rental months.

A period of medical need ends when Parenteral and Enteral Nutrients are not medically necessary for two consecutive months. Voluntary nonbilling and institutional care for two or more months does not affect the 15-month period. We will resume calculating the 15-month period when the patient is released from the hospital. You cannot file for an entire month's rental when the patient is hospitalized during the month. Medicare may request documentation verifying a break in medical need of two months or more before we will approve an additional 15-month rental period.

A new 15-month period does not begin when the patient changes suppliers. The new supplier is entitled to the balance remaining on the 15-month rental period. Suppliers must continue supplying the patient with a pump after the 15-month rental is completed, as long as the pump is medically necessary.

The patient (or responsible party) decides whether to rent or purchase the pump. Effective April 1, 1990, Medicare will not cover the purchase of a pump that has met the 15-month rental limit unless the ordering physician switches the prescription between Parenteral and Enteral Nutrients.

The total rental payments will be subtracted from the reasonable charge when a pump is purchased before the 15-month rental period is met. Medicare will not continue rental payments after the pump is purchased. In addition, Palmetto Government Benefits Administrators reserves the right to request written authorization from the patient for a pump purchase.

The following modifiers must be used on claims for PEN pumps:

KH	Initial claim, purchase or first month rental, capped rental items and/or PEN pumps
KI	Second or third month rental, capped rental items and/or PEN pumps
KJ	Months four to fifteen, capped rental items and/or PEN pumps

Medicare will allow maintenance and servicing payments once the 15-month rental period is completed. The maintenance charge will equal one-half month's rental. Use modifier "MS" with the appropriate pump procedure code when filing a claim for the maintenance charge. If the patient met the 15-month limit before April 1, 1990, maintenance charges may be reimbursed for claims with service dates of October 1, 1990 or after. Medicare will pay maintenance for Enteral Nutrition pumps every six months and every three months for Parenteral Nutrition pumps; if the maintenance or service actually was provided.

Blenderized Formulas

Justification for use and higher reimbursement of blenderized formulas must be indicated on the Certificate of Medical Necessity form. Blenderized formulas (B4151) will be reimbursed at the Category I (B4150) rate in the absence of medical justification.

A higher reimbursement rate will be made only when:

- The beneficiary has demonstrated an intolerance to semisynthetic formulas, or
- The attending physician submits documentation, which may include hospital or other medical records, demonstrating medically justifiable contraindications to semi-synthetics.

Patients Receiving Less Than 20 or More Than 35 Calories/kg

Most patients require between 20 and 35 calories/kg per day to maintain weight and strength. If a patient falls outside this range, the certification should document the medical reason why. The calculation for determining the patient's intake of calories/kg takes the patient's weight into consideration. This formula is provided on page 63.3 and 63.4..

Nutrients Other Than Blenderized, Semi-Synthetics or Category II Formulas

If a patient has been prescribed an Enteral Nutrition formula in Categories III-VI, justification for use of these formulas must be indicated on the CMN. The physician must indicate what medical reason necessitates the need for the higher level nutrient or why the patient could not be maintained on a Category I Semi-synthetic nutrient.

Intravenous (IV) Poles in the "Home" Setting
IV poles are reimbursed under PEN Medicare coverage for places of service 12 (Home), 31 (SNF), 32 (NF), 33 (Custodial Care Facility) or 54 (Intermediate Care Facility/Mentally Retarded), effective 10/1/93. For services rendered prior to this date, IV poles used in conjunction with PEN therapy are only covered in the home setting.

Skilled Nursing Facility (SNF) Patients
The Skilled Nursing Facility (SNF) has the option to furnish PEN nutrients and supplies directly or through an outside supplier (pharmacy, manufacturer, etc.).

Enteral nutrition provided to a patient in a Part A covered stay must be billed by the SNF to the fiscal intermediary. No payment from Part B is available when enteral nutrition services are furnished to a beneficiary in a stay covered by Part A. However, if a beneficiary is in a stay not covered by Part A, enteral nutrition is eligible for coverage under Part B. In this situation, if the enteral nutrition is furnished by an outside supplier, it is billed to the DMERC; if it is furnished by the SNF, it may be billed to the fiscal intermediary or to the DMERC, *but not both.*

If the SNF chooses to furnish the nutrients and supplies directly, the following distinction must be made:

- When the Medicare beneficiary is an inpatient with Medicare Part A coverage, the SNF bills the Medicare Part A Fiscal Intermediary on a reasonable cost basis. Parenteral Nutrition therapy is classified as ancillary service, and Enteral Nutrition therapy is classified as routine dietary cost for Medicare reporting purposes.
- When the Medicare beneficiary is in a long-term care facility with Medicare Part B coverage only, the SNF bills the DMERC. These claims must be submitted to the appropriate DMERC based on the patient's permanent address.

Hospital Inpatients
When a patient is in the hospital as an inpatient covered under Medicare Part A, the PEN therapy for that stay is reimbursed under the DRG payment rate by the Medicare Part A intermediary.

When a hospital supplies PEN therapy to an inpatient who is not covered by Medicare Part A and meets the criteria for coverage under the prosthetic device benefit under Medicare Part B, the claim with all necessary

documentation must be sent by the hospital to the DMERC. It must be indicated that the beneficiary is not covered under Medicare Part A Hospital Plan.

Special PEN Billing Instructions for Reporting "Days," "Grams of Protein" or "Units"

Reporting Units of PEN Formulas
For all nutrients and solutions billed, the date range for the Dates of Service should always correspond to the actual number of days billed. If the data does not match, we will check for a change in orders. If a revision certification is not attached, your claim will be denied for either a revised certification form or to verify the number of units billed. All Enteral Nutrient codes are established in 100 calorie increments, therefore, they must be billed and processed in 100 calorie increments -- one unit for every 100 calories supplied.

For Enteral Nutrients, always indicate the number of units supplied. Calculate as follows:

Number of Calories Prescribed* ÷ 100 x *Number of Days Billed=Number of Units

Example:
Prescribed calories --
1500 per day for 30 days (one month)

1500 *Calories* ÷ 100 x 30 *Days*=450 *Units*

Monthly Units=450

If a physician orders more than one nutrient in the same category, the charges must be combined with the caloric units for these nutrients on one line. Each nutrient and the calories per day must be listed separately on the certification form.

Example:
The certification indicates Osmolite at 750 calories per day and Ensure at 750 calories per day. Both nutrients are in the same category and should be coded as B4150, combined and submitted as follows:

1500 *Calories* ÷ 100 x 30 *Days* = 450 *Units*

Date of Service	Code	Units
01/01/92-01/31/92	B4150	450

For TPN solutions, always indicate the number if days infused.

Calculating Calories/Kg
To determine if a patient is receiving less than 20 calories/Kg or more than 35 calories/Kg, the following calculations must be done. If the patient's

intake falls outside this range, an explanation should be documented on the CMN form. The patient's weight in pounds must be converted to kilograms by dividing the weight in pounds by 2.2 (the number of kilograms in one pound):

Weight (lbs) ÷ 2.2 = Weight in Kilograms

Then the prescribed number of calories per day should be divided by the patient's weight in kilograms. This indicates the number of calories/Kg the patient is infusing:

Prescribed Calories ÷ Weight (Kg) = Calories/Kg

PEN Supply and Administration Kits
Payment for supply and administration kits are based on a per diem rate. The total number of actual days used should be entered in Item 24G of the CMS-1500 (12/90) form or in the Days/Units field for EMC transmission.

Pumps and Intravenous (IV) Poles
The number of units for pump and IV pole is always "1" if billing for a one month period. If billing for a service charge that is less than your usual and customary charge, use modifier-52 with the appropriate procedure code in Item 24D, and show "1" in Item 24G of the CMS-1500 (12/90) form.

Enteral Nutrition Tubes
For Enteral Nutrition tubes, show the actual number of tubes provided.

Reporting Parenteral Nutrition Grams of Protein
Pre-mixed solutions, grams of protein or amino acid per day must be reported on the certification form. To convert volume and concentration to grams of protein, the following formula must be used:

Milliliters of Solution ÷ 100 x Concentration = Grams of Protein

Fractions of a gram are always rounded up to the next whole gram.

Example: Prescription is for Travasol 8.5%, 750 ml per day

750 *ml* ÷ 8.5 = 63.75 *Rounded to* 64 *Grams of Protein per Day*

The grams of amino acid determines which procedure code will be used to bill the TPN solution.

Reporting Units of Lipids
For proper payment of lipids, use the following formula:

***Milliters of Lipids* x *Number of Infusions (Of Lipids) During Billing Period* ÷ 500**

NOTE: Lipids are billed by number of units. 500ml of lipids=1 unit.

Example: Prescription is for 400ml of lipids, three times/week and billed for a 31 day month.

400*ml* x 13 *Infusions* ÷ 500 = 10 *Units*

Special Parenteral Nutrition Solutions
Unlike the method of reporting units as days for other pre-mixed solutions, units for special solutions (codes B5000, B5100, and B5200) are reported in Item 24G of the CMS-1500 (12/90) form as grams per day multiplied by number of days.

Example: Prescription is for Nephramine 5.4%, 250 ml per day and billed for the month of April 1996.

250 ÷ 100 x 5.4 = 13.5 *Rounded to* 14 x 30 *Days*= 420 *Units*

Date	Place	Code	Charge	Units
04/01/92-04/30/92	12	B5000	$3,500.00	420

NOTE: Medicare will only pay for a one-month supply at a time.

NOTE: Span dates (i.e., a span of time between the "from" and "to" dates of service) are required when billing for enteral nutrition formulae, parenteral solutions and all supply kits.

Intra-peritoneal Nutrition
The DMERC Regional Medical Review Policy on Parenteral Nutrition defines parenteral nutrition as the provision of nutritional requirements intravenously. When billing nutrients, supplies or pumps that are used for intra-peritoneal nutrition (sometimes associated with peritoneal dialysis), use HCPCS code B9999 (Not Otherwise Classified for parenteral supplies). Do not use the specific B codes for parenteral nutrients based on protein content, etc., when nutrients are used in this fashion.

The calorie requirement stating "Most patients require between 20 and 35 calories/kg per day to maintain weight and strength" has been eliminated effective 4/01/02.

<<<BACK

Region C DMEPOS Supplier Manual (updated through Autumn 2002)
....Change of Address Notification Form
....Contents
....Index
....Part I - General Information
.....Chapter 1 - Beneficiary Eligibility & Supplier Responsibility
.....Chapter 2 - Jurisdiction
.....Chapter 3 - National Supplier Clearinghouse
.....Chapter 4 - Statistical Analysis DMERC
.....Chapter 5 - Claims Filing
.....Chapter 6 - Documentation Requirements
.....Chapter 7 - Advance Beneficiary Notice
.....Chapter 8 - Durable Medical Equipment
.....Chapter 9 - Pricing

General Information
Supplier Enrollment
Ombudsman Contacts
FAQs
Coverage
Certificates of Medical Necessity
Physician Information Sheets
SADMERC
Advisories
Manuals
Medical Policies
Fee Schedules
Forms
Appeals
Benefit Integrity
Learning & Education
Related Sites
DMERC Home
Providers Home

Manuals

<<BACK

Chapter 64 - Enteral Nutrition

View Attachments

Chapter 64 contains the medical policy for enteral nutrition. Click on View Attachments to download the entire chapter for viewing and printing in PDF format.

MEDICAL POLICY

SUBJECT: Enteral Nutrition

HCPCS CODES

The appearance of a code in this section does not necessarily indicate coverage.

A5200	Percutaneous catheter/tube anchoring device, adhesive skin attachment
A9270	Non-covered item or service
B4034	Enteral feeding supply kit; syringe, per day
B4035	Enteral feeding supply kit; pump fed, per day
B4036	Enteral feeding supply kit; gravity fed, per day
B4081	Nasogastric tubing with stylet
B4082	Nasogastric tubing without stylet
B4083	Stomach tube - levine type
B4086	Gastrostomy/jejunostomy tube, any material, any type (standard or low profile), each
B4150	Enteral formulae; category I; semi-synthetic intact protein/protein isolates, administered through an enteral feeding tube, 100 calories = 1 unit
B4151	Enteral formulae; category I; natural intact protein/protein isolates, administered through an enteral feeding tube, 100 calories = 1 unit

B4152	Enteral formulae; category II; intact protein/protein isolates (calorically dense), administered through an enteral feeding tube, 100 calories = 1 unit
B4153	Enteral formulae; category III; hydrolyzed protein/amino acids, administered through an enteral feeding tube, 100 calories = 1 unit
B4154	Enteral formulae; category IV; defined formula for special metabolic need, administered through an enteral feeding tube, 100 calories = 1 unit
B4155	Enteral formulae; category V; modular components, administered through an enteral feeding tube,100 calories = 1 unit
B4156	Enteral formulae; category VI; standardized nutrients, administered through an enteral feeding tube, 100 calories = 1 unit
B9000	Enteral nutrition infusion pump - without alarm
B9002	Enteral nutrition infusion pump - with alarm
B9998	NOC for enteral supplies
E0776	IV pole

HCPCS MODIFIERS

XA	IV pole used in conjunction with parenteral or enteral nutrition

BENEFIT CATEGORY: Prosthetic Device

REFERENCES: Coverage Issues Manual 65-10

DEFINITION
Enteral nutrition is the provision of nutritional requirements through a tube into the stomach or small intestine.

COVERAGE AND PAYMENT RULES
For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, "reasonable and necessary" are defined by the following coverage and payment rules.

General
Enteral nutrition is covered for a patient who has (a) permanent non-function or disease of the structures that normally permit food to reach the small bowel or (b) disease of the small bowel which impairs digestion and absorption of an oral diet, either of which requires tube feedings to provide

sufficient nutrients to maintain weight and strength commensurate with the patient's overall health status.

The patient must have a permanent impairment. Permanence does not require a determination that there is no possibility that the patient's condition may improve sometime in the future. If the judgement of the attending physician, substantiated in the medical record, is that the condition is of long and indefinite duration (ordinarily at least 3 months), the test of permanence is considered met. Enteral nutrition will be denied as non-covered in situations involving temporary impairments.

The patient's condition could be either anatomic (e.g., obstruction due to head and neck cancer or reconstructive surgery, etc.) or due to a motility disorder (e.g., severe dysphagia following a stroke, etc.). Enteral nutrition is non-covered for patients with a functioning gastrointestinal tract whose need for enteral nutrition is due to reasons such as anorexia or nausea associated with mood disorder, end-stage disease, etc.

The patient must require tube feedings to maintain weight and strength commensurate with the patient's overall health status. Adequate nutrition must not be possible by dietary adjustment and/or oral supplements. Coverage is possible for patients with partial impairments --e.g., a patient with dysphagia who can swallow small amounts of food or a patient with Crohn's disease who requires prolonged infusion of enteral nutrients to overcome a problem with absorption.

Enteral nutrition products that are administered orally and related supplies are noncovered.

If the coverage requirements for enteral nutrition are met, medically necessary nutrients, administration supplies, and equipment are covered.

No more than one month's supply of enteral nutrients, equipment or supplies is allowed for one month's prospective billing. Claims submitted retroactively, however, may include multiple months.

The ordering physician is expected to see the patient within 30 days prior to the initial certification. If the physician did not see the patient within this timeframe, he/she must document the reason why and describe what other monitoring methods were used to evaluate the patient's enteral nutrition needs.

Enteral nutrition provided to a patient in a Part A covered stay must be billed by the SNF to the fiscal intermediary. No payment from Part B is available when enteral nutrition services are furnished to a beneficiary in a stay covered by Part A. However, if a beneficiary is in a stay not covered by Part A, enteral nutrition is eligible for coverage under Part B. In this situation, if the enteral nutrition is furnished by an outside supplier, it is billed to the DMERC; if it is furnished by the SNF, it may be billed to the fiscal intermediary or to the DMERC, *but not both*.

Nutrients
Enteral formulas consisting of semi-synthetic intact protein/protein isolates (B4150) are appropriate for the majority of patients requiring enteral nutrition. Formulas consisting of natural intact protein/protein isolates, code B4151, are covered for patients with an allergy or intolerance to semi-synthetic formulae (B4150). Calorically dense formulas (B4152) are covered if they are ordered and are medically necessary. The medical necessity for special enteral formulas (B4151, B4153–B4156) will need to be justified in each patient. If the medical necessity for these formulas is not substantiated, payment will be based on the allowance for the least costly alternative, code B4150.

Baby food and other regular grocery products that can be blenderized and used with the enteral system will be denied as non-covered.

Equipment and Supplies
Enteral nutrition may be administered by syringe, gravity, or pump. Some enteral patients may experience complications associated with syringe or gravity method of administration. If a pump (B9000-B9002) is ordered, there must be documentation accompanying the CMN to justify its use (e.g., gravity feeding is not satisfactory due to reflux and/or aspiration, severe diarrhea, dumping syndrome, administration rate less than 100 ml/hr, blood glucose fluctuations, circulatory overload, jejunostomy tube used for feeding). If the medical necessity of the pump is not documented, the pump will be denied as not medically necessary.

The feeding supply kit (B4034-B4036) must correspond to the method of administration indicated in question 13 of the Certificate of Medical Necessity. If it does not correspond, payment for the billed code will be based on the allowance for the code relating to the method of administration specified on the CMN or the billed code, whichever is less. If a pump supply kit (B4035) is ordered and the medical necessity of the pump is not documented, payment will be based on the allowance for the least costly alternative, B4036.

Payment for a catheter/tube anchoring device is considered included in the allowance for enteral feeding supply kits (B4034-B4036). Code A5200 should not be billed separately and is not paid in addition to the supplies for enteral nutrition.

More than three nasogastric tubes (B4081-B4083), or one gastrostomy/jejunostomy tube (B4086) every three months is rarely medically necessary.

CODING GUIDELINES
When enteral nutrition is covered, dressings used in conjunction with a gastrostomy or enterostomy tube are included in the supply kit code (B4034-B4036) and should not be billed separately using dressing codes.

When an IV pole (E0776) is used for enteral nutrition administered by gravity or a pump, the XA modifier should be added to the code.

Codes B4150-B4156 may only be used for enteral nutrients delivered through an enteral feeding tube. Enteral nutrients administered by mouth must be billed A9270 if a claim is submitted.

Categories of enteral nutrition are based on the composition and source of ingredients in each enteral nutrient product. Suppliers should refer to the Enteral Nutrition Product Classification List on the Statistical Analysis DME Regional Carrier (SADMERC) Web site or contact the SADMERC for guidance on the correct coding for these items. Only those products included in the Product Classification List published by the DMERCs may be billed using code B4154 or B4155. If a manufacturer or supplier thinks that another product meets the definition of this code, they should contact the SADMERC for a coding determination. The SADMERC must issue a written determination approving use of code B4154 or B4155 before either may be used for a new product or a product not listed on the Enteral Nutrition Product Classification List.

DOCUMENTATION

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. §13951(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

With initial claims for enteral nutrition formulas and pumps, a certificate of medical necessity (CMN) must be submitted to the DMERC. Section B of the CMN for enteral nutrition may be completed by someone other than the treating physician, so long as it is not anyone in a financial relationship with the supplier. However, the CMN must be reviewed for the accuracy of the information and signed and dated by the treating physician to indicate agreement. The CMN for enteral nutrition is HCFA Form 853.

A new Initial certification for enteral nutrients is required when (1) a formula billed with a different code which has not been previously certified is ordered, or (2) enteral nutrition services are resumed after they have not been required for two consecutive months. A new Initial Certification for a pump (B9000 or B9002) is required if enteral nutrition services involving use of a pump are resumed after they have not been required for two consecutive months. An Initial Certification is also required for a pump if a patient receiving enteral nutrition by the syringe or gravity method is changed to administration using a pump. (In this latter situation, a Revised Certification is required for the nutrient which indicates the change to the

pump method of administration--Question #13 on the CMN.)

In addition to the reason listed above, a Revised Certification is required when, for a formula which has been previously certified, (1) the number of calories per day is changed, or (2) number of days per week administered is changed, or (3) the method of administration (syringe, gravity, pump) changes, or (4) route of administration is changed from tube feedings to oral feedings (if billing for denial), or (5) if a Category IV or V enteral nutrient being provided is changed. The initial date listed in Section A of a Revised CMN for codes B4154 or B4155 must match the initial date on the certification record for code B4154 or B4155 which has been set up by the DMERC.

Regularly scheduled recertifications are not required. However, a recertification is required if the physician indicates a length of need of less than lifetime (i.e., less than 99 months) on the CMN and subsequently orders a greater length of need. Recertification may also be requested on an individual basis at the discretion of the DMERC.

The Initial Certification must be accompanied by adequate documentation to support the medical necessity of the following orders, if applicable:

1. the need for special nutrients (B4151, B4153–B4156),
2. the need for a pump.

Each claim submitted with code B4154 or B4155 must include the product name of the nutrient which is provided. This should be entered in the HA0 record of an electronic claim or attached to a hard copy claim.

If two Category IV or two Category V nutrients are being provided at the same time, they should be billed on a single claim line with the units of service reflecting the total calories of both nutrients.

When a certification is required, the claim must include a copy of the CMN if filed as a hard copy. If the claim is filed electronically, the information on the CMN must be transcribed exactly into the GU0 record. (See DMEPOS National Standard Format Matrix for details.) The HA0 record can be used for additional narrative documentation that will not fit on the GU0 record.

Refer to the Supplier Manual for more information on orders, CMNs, medical records, and supplier documentation.

EFFECTIVE DATE: Claims with dates of service on or after April 1, 2002.

This is a revision to a previously published policy.

To download a printable version of the Certificate of Medical Necessity for enteral nutrition (DMERC 10.02B; HCFA-853 (4/96)), click on View

Attachments above.

<<<BACK